GSA

JUN 15 2005

GSA Office of the Chief Acquisition Officer

MEMORANDUM FOR JULIA WISE
DIRECTOR
CONTRACT POLICY DIVISION

FROM: RALPH J. DESTEFANO, DIRECTOR
REGULATORY AND FEDERAL ASSISTANCE
DIVISION

SUBJECT: GSAR Case 2005-G501, Federal Agency Retail Pharmacy Program

Attached are comments received on the subject GSAR case published at 70 FR 19045; April 12, 2005. The comment closing date was June 13, 2005.

Response Number	Date Received	Comment Date	Commenter
2005-G501-1	06/13/05	06/07/05	Sanofi Aventis
2005-G501-2	06/09/05	06/09/05	Coalition for Government Procurement
2005-G501-3	06/13/05	06/13/05	Wyeth Pharmaceuticals
2005-G501-4	06/13/05	06/13/05	Epstein Becker & Green, P.C.
2005-G501-5	06/13/05	06/13/05	Tyco Healthcare Mallinckrodt Pharmaceuticals
2005-G501-6	06/13/05	06/13/05	GlaxoSmithKline

U.S. General Services Administration
1800 F Street, NW
Washington, DC 20405-0002
www.gsa.gov

Response Number	Date Received	Comment Date	Commenter
2005-G501-7	06/13/05	06/13/05	PHRMA
2005-G501-8	06/13/05	06/13/05	Merck & Co., Inc
2005-G501-9	06/22/05	06/13/05	ABA

Attachments

DEPARTMENT OF VETERANS AFFAIRS
Office of General Counsel
PO Box 76
Hines IL 60141

In Reply Refer To:

October 14, 2004

Dear Manufacturer of Covered Drugs:

As you are aware, the Veterans Health Care Act of 1992 (VHCA), P.L. 102-585, Section 603 (38 U.S.C. 8126), and the Master Agreement (MA) and Pharmaceutical Pricing Agreement (PPA) that your company signed with the Department of Veterans Affairs (VA), require that Federal ceiling prices (FCPs) must be applied to covered drugs purchased by the Department of Defense (DoD) through depot contracting systems. TRICARE Management Activity (TMA) is the DoD organization established to manage DoD's comprehensive health care program known as TRICARE, which includes an alternate health care system mandated by Congress for U.S. armed forces personnel, retirees, and dependents who do not reside near a military treatment facility. (See Chapter 55, Title 10, United States Code.) The TRICARE program involving health care furnished outside of military treatment facilities has traditionally been implemented through contracts with large civilian managed health care organizations, which, in the past, provided pharmaceuticals to DoD beneficiaries with no direct involvement by DoD officials. Under this prior approach, TRICARE regional contractors entered into their own agreements with providers of pharmaceuticals, and DoD did not directly or indirectly control payments for its TRICARE beneficiaries' drugs. Furthermore, DoD was not entitled to receive each dollar saved, had managed care contractors been permitted to buy drugs and prescriptions at Government discounts. Under these circumstances, VA determined that the VHCA requirement for a depot contracting system did not exist and TRICARE was not able to benefit from Federal covered drug pricing through its original managed care contracts. (See "Dear Manufacturer letter" of October 7, 1996.)

Effective May 3, 2004, TRICARE restructured its Pharmaceutical Benefit Program in response to congressional direction to redesign the military and contractor pharmacy system. It carved the benefit out of its regional contracts, set up a DoD Pharmacy Benefit Office to control payments for beneficiary scripts and hired a Pharmacy Benefits Manager (PBM) to handle most administration work involved in contracting with a large number of retail pharmacies (collectively, "the network") to fill TRICARE beneficiary scripts. TMA followed commercial models in devising its new plan, allowing network pharmacies to

Dear Manufacturer of Covered Drugs

obtain drugs in the usual fashion and then applying the Federal discount after scripts were filled, through refund claims submitted to manufacturers by the PBO itself. This approach eliminated the possibility that commercial contractors or subcontractors of DoD might profit from application of FCPs to TRICARE purchases.

TMA presented the restructuring plan to VA in 2002, with a request that VA approve application of FCPs to TMA purchases of covered drugs obtained by its beneficiaries from subcontracted retail pharmacies. On October 24, 2002, after consideration of the functional elements and the legal issues inherent in the plan, the Secretary of VA decided that TMA's Retail Pharmacy Benefit Plan (TRRx) was a centralized pharmaceutical commodity management system that met the definition of "depot" contracting system set forth in 38 U.S.C. 8126(h)(3). Consequently, covered drug prescription purchases under TRRx, authorized and paid for by TMA's Pharmacy Benefits Office, qualified for FCPs from commencement of the TRRx program on June 1, 2004. However, to avoid complicating and delaying manufacturers' 2004 annual non-FAMP reports, TMA has agreed not to demand refunds resulting from application of FCPs to retail network purchases until after September 30, 2004, the cut-off date for transactions included in the 2004 reports.

It is within the authority of the VA Secretary, in administration of the VHCA and as issuer of the MAs and PPAs, to determine whether one of the four VHCA Federal agencies has established a qualifying depot contracting system under which covered drugs may be purchased at a discount. (See 38 U.S.C. 8126(a), (e)(3) & (4), (f), (g), and (h)(5).) Once that determination is made, the Federal agency (in this case, DoD) is authorized to receive FCPs on covered drugs by operation of law and the express terms of the Master Agreement executed by VA and each drug manufacturer. No published notice or rulemaking is required to make effective the policy and requirements already established by statute and written agreements.

Because TMA's retail pharmacy network covered drug purchases will be made initially at commercial prices, TMA will obtain Federal ceiling pricing for these purchases by forwarding detailed purchase data to manufacturers each month and then requesting refunds on a quarterly basis to achieve Federal pricing. TMA's plan for transmitting data and collecting refunds is set forth at the TMA web site: http://www.tricare.osd.mil/pharm_mfg/default.cfm,

In addition to calculating covered drug refunds using TMA's monthly purchase data feeds, manufacturers who sell and/or deliver their drugs to network pharmacies and others through wholesalers will need to adjust their

Dear Manufacturer of Covered Drugs

sales data used in current non-FAMP computations in order to ensure that TMA purchases are properly reclassified as sales to the Government. Once TMA identifies aggregate purchases of NDC packages of covered drugs as Government purchases, manufacturers will have to remove these purchases from net wholesale sales in order to arrive at correct non-FAMP figures for each NDC of each drug. Manufacturers may assume that TMA's reported purchases occurred during the non-FAMP reporting period in which the TMA data was received. Except for adjusting the third-quarter 2004 non-FAMP in Nov. 2005, and except to correct fundamental computation errors in later quarters, there will be no requirement to re-open and adjust already filed non-FAMP reports to accommodate TMA data received after filing. Accounting methods for removing TMA purchases from wholesale sales may vary by company, depending on systems set-up. Please find attached to this letter some "Non-FAMP Calculation Considerations" and "Non-FAMP Impact Scenarios" to assist you with devising a method for removing TMA purchases from wholesale sales.

If you have any questions concerning the above policies, please telephone Mel Noel at (708) 786-5167.

Sincerely,

Steven Thomas
Acting Executive Director
VA National Acquisition Center

1 Enclosure

Non-FAMP CalculationConsiderations

- If TRRx sales included product delivered through wholesalers (as opposed to direct sales to pharmacies) and Mfg uses wholesale sales to compute non-FAMPs, then these TRRx sales and units must be removed from wholesale sales during current non-FAMP calculations
- If products sold to TRRx were originally booked as direct sales to a retail chain, it is likely that these sales were already excluded from the non-FAMP calculation
- If the TRRx transactions cause anomalies in the non-FAMP that are not taken care of through the normal chargeback smoothing methodology, communicate those issues to Mel Noel at the National Acquisition Center for consideration.

Non-FAMP Impact Scenarios

- **Scenario 1, Method 1**
  - Manufacturer sells only to Wholesalers
  - Manufacturer has no contractual agreements with the retail pharmacies
  - Manufacturer normally removes Federal sales by adjusting wholesale sales at contract selling price, in this case the assumed FCP of $72
  - In absence of known sale price to TRRx Network, the manufacturer calculates TRRx refund using Non-FAMP = $94.74
  - TRRx reports to manufacturer that retail pharmacies purchased 1,250 units of the NDC
  - Given the assumptions the actual refund to Tricare would be 1,250 x ($94.74-$72.00) = $28,425
  - When the manufacturer does not know the price to the retailer, the refund amount to Tricare that was figured based on non-FAMP cannot be used to re-state the non-FAMP.
  - The amount used to restate the non-FAMP must be at WAC.
  - The fact that Tricare has given Manufacturers a lesser price (Non-FAMP) to calculate the refund cannot translate to an assumption that the original sale occurred at other than WAC

- **Changes to non-FAMP (Scenario 1, Method 1)**
  - Government sales at FCP are increased by 1,250 units at $72.00, units are increased by 1,250
  - An additional reduction is made to account for the TRRx refund which is the difference between WAC and the FCP times the number of units or ($100-$72) x 1,250 = $35,000

Original Calculation

	Dollars	Units
Wholesale Sales (WAC = $100)	$10,000,000.00	100,000
Less:		
Prompt Pay Discount (2%)	$200,000.00	
Government Sales @ $72.00	$360,000.00	5,000
PHS (@ 602 price $75.00)	$2,250.00	30
Chargebacks	$523,075.00	
Subtotal Reductions	$1,085,325.00	
Non-Federal Dollars & Units	$8,914,675.00	94,970
non-FAMP	$93.87	

Revised Calculation

	Dollars	Units
Wholesale Sales (WAC = $100)	$10,000,000.00	100,000
Less:		
Prompt Pay Discount (2%)	$200,000.00	
Government Sales @ $72.00	$450,000.00	6,250
PHS (@ 602 price $75.00)	$2,250.00	30
Chargebacks	$523,075.00	
TRRx Refund @ WAC	$35,000.00	
Subtotal Reductions	$1,210,325.00	
Non-Federal Dollars & Units	$8,789,675.00	93,720
non-FAMP	$93.79	

- **Scenario 1, Method 2**
  - Manufacturer sells only to Wholesalers
  - Manufacturer has no contractual agreements with the retail pharmacies
  - Manufacturer normally removes Federal sales by adjusting wholesale sales and chargebacks
  - The FCP = $72
  - In the absence of known sales price to TRRx Network, Manufacturer uses Non-FAMP = $94.74

- **Changes to non-FAMP (Scenario 1, Method 2)**
  - Government sales at "WAC" is increased by 1,250 x $100.00, Units are increased by 1,250
  - The TRRx refund for bookkeeping purposes is calculated as in Method 1.
  - No further adjustment is necessary because the chargeback system is not affected by the transaction.

Original Calculation

	Dollars	Units
Wholesale Sales (WAC = $100)	$10,000,000.00	100,000
Less:		
Prompt Pay Discount (2%)	$200,000.00	
Government Sales (@ WAC)	$500,000.00	5,000
PHS (@ WAC)	$3,000.00	30
Chargebacks	$523,075.00	
(Less Gov and PHS Chargebacks)	-$140,750.00	
Subtotal Reductions	$1,085,325.00	
Non-Federal Dollars & Units	$8,914,675.00	94,970
non-FAMP	$93.87	

Revised Calculation

	Dollars	Units
Wholesale Sales (WAC = $100)	$10,000,000.00	100,000
Less:		
Prompt Pay Discount (2%)	$200,000.00	
Government Sales (@ WAC)	$625,000.00	6,250
PHS (@ WAC)	$3,000.00	30
Chargebacks	$523,075.00	
(Less Gov and PHS Chargebacks)	-$140,750.00	
Subtotal Reductions	$1,210,325.00	
Non-Federal Dollars & Units	$8,789,675.00	93,720
non-FAMP	$93.79	

- **Scenario 2, Method 1**

  - Manufacturer sells only to Wholesalers
  - Manufacturer has agreement with the retail pharmacy at a sales price of $95.00
  - Manufacturer normally removes Federal sales by adjusting wholesale sales at Government contract selling price, in this case the FCP = $72
  - TRRx reports to manufacturer that retail pharmacies purchased 1,250 units of the NDC
  - Given the assumptions (wholesale sales only, known contract price to retail pharmacy) the actual refund to Tricare would be 1,250 x ($95.00-$72.00) = $28,750
  - When the manufacturer knows the price to the retailer, those transactions will need to be replaced with Tricare transactions.

- **Changes to non-FAMP (Scenario 2, Method 1)**

  - The chargeback transactions are decreased by the chargebacks for those units now classified as Tricare (1,250 x $5.00 = $6,250)
  - An additional reduction is made to account for the TRRx refund which is (for bookkeeping purposes in this scenario) the difference between WAC and the FCP times the number of units or ($100-$72) x 1,250 = $35,000
  - The fact that Tricare has given Manufacturers a lesser price (pharmacy contract price) to calculate the refund cannot translate to an assumption that the original sale occurred at other than WAC.

Original Calculation

	Dollars	Units
Wholesale Sales (WAC = $100)	$10,000,000.00	100,000
Less:		
Prompt Pay Discount (2%)	$200,000.00	
Government Sales @ $72.00	$360,000.00	5,000
PHS (@ 602 price $75.00)	$2,250.00	30
Chargebacks	$523,075.00	
Subtotal Reductions	$1,085,325.00	
Non-Federal Dollars & Units	$8,914,675.00	94,970
non-FAMP	$93.87	

Revised Calculation

	Dollars	Units
Wholesale Sales (WAC = $100)	$10,000,000.00	100,000
Less:		
Prompt Pay Discount (2%)	$200,000.00	
Government Sales @ $72.00	$450,000.00	6,250
PHS (@ 602 price $75.00)	$2,250.00	30
Chargebacks	$516,825.00	
TRRx Refund @ WAC	$35,000.00	
Subtotal Reductions	$1,204,075.00	
Non-Federal Dollars & Units	$8,795,925.00	93,720
non-FAMP	$93.85	

- **Scenario 2, Method 2**
  - Manufacturer sells only to Wholesalers
  - Manufacturer has contractual agreements with the retail pharmacies at a sales price of $95
  - Manufacturer normally removes Federal sales by adjusting wholesale sales and chargebacks
  - The FCP = $72; Non-FAMP = $94.74

- **Changes to non-FAMP (Scenario 2, Method 2)**
  - Government sales at "WAC" is increased by 1,250 x $100.00, Units are increased by 1,250
  - The TRRx refund for bookkeeping purposes is calculated as in Method 1.
  - No further adjustment is necessary because the chargeback system is not affected by the transaction

Original Calculation

	Dollars	Units
Wholesale Sales (WAC = $100)	$10,000,000.00	100,000
Less:		
Prompt Pay Discount (2%)	$200,000.00	
Government Sales (@ WAC)	$500,000.00	5,000
PHS (@ WAC)	$3,000.00	30
Chargebacks	$523,075.00	
(Less Gov and PHS Chargebacks)	-$140,750.00	
Subtotal Reductions	$1,085,325.00	
Non-Federal Dollars & Units	$8,914,675.00	94,970
non-FAMP	$93.87	

Revised Calculation

	Dollars	Units
Wholesale Sales (WAC = $100)	$10,000,000.00	100,000
Less:		
Prompt Pay Discount (2%)	$200,000.00	
Government Sales (@ WAC)	$625,000.00	6,250
PHS (@ WAC)	$3,000.00	30
Chargebacks	$516,825.00	
(Less Gov and PHS Chargebacks)	-$140,750.00	
Subtotal Reductions	$1,204,075.00	
Non-Federal Dollars & Units	$8,795,925.00	93,720
non-FAMP	$93.85	

WHITE PAPER FOR THE OFFICE OF THE SECRETARY
TRICARE AND FEDERAL CEILING PRICES

OCTOBER 10, 2002

PURPOSE:

To inform the Secretary of the facts and circumstances surrounding a decision of the VA P.L. 102-585, Sec. 603, Policy Group at its September 24, 2002, annual meeting regarding requests for favorable interpretation of the P.L. received from DoD's TRICARE Management Activity (TMA) between September 17, 2001, and June 28, 2002. TMA has asked that VA concur in its opinion that purchases of covered drugs under the retail portion of the new TRICARE Pharmacy Benefits Program (TPBP) qualify for Federal Ceiling Prices (FCP) under the P.L. (Veterans Health Care Act of 1992; 38 U.S.C. 8126).

POLICY GROUP DECISION:

After considering TMA's position and a PhRMA letter opposing the idea, the Policy Group agreed that TMA's interpretation of the P.L. was reasonable and that DoD beneficiary prescriptions filled under the retail portion of the new TPBP will qualify for Federal Ceiling Prices. (The Policy Group includes representation from all the elements of VA that are stakeholders in the drug pricing statute, i.e., VHA's PBM, OA&MM's NAC, the Office of Inspector General (52C), and the Office of General Counsel (025).

DISCUSSION OF LEGAL QUESTIONS:

There can be no real question that, when Congress enacted P.L. 102-585, Sec. 603, in 1992, their inclusion of DoD as one of the benefiting Federal activities meant that Congress expected all DoD expenditures for covered drugs to be affected by the calculations which yield Federal Ceiling Prices. The questions that arise have to do with the strict or liberal interpretation of the statute's wording that describes the acquisitions that are the subjects of a Master Agreement (MA) and Pharmaceutical Pricing Agreement (PPA). The statute, at Sec. 8126(a)(2), sets forth one of the requirements of the MA as follows: "with respect to each covered drug of the manufacturer procured by a Federal agency described in subsection (b) [including DoD] on or after January 1, 1993, that is purchased under depot contracting systems or listed on the Federal Supply Schedule, the manufacturer has entered into and has in effect a pharmaceutical pricing agreement with the Secretary ..."

The primary legal issue is whether a DoD Pharmacy Benefits Office (PBO) mechanism for filling DoD beneficiary prescriptions through a commercial retail pharmacy network and contracted pharmacy benefits management firm (PBM) constitutes a purchase by DoD under a depot contracting system.

1. The definition of depot in Sec. 8126(h)(3) asserts that "depot" means a "centralized commodity management system through which covered drugs procured by an agency of the Federal Government are-- (A) received, stored, and delivered through-- (i) a federally owned and operated warehouse system, or (ii) a commercial entity operating under contract with such agency; or (B) delivered directly from the commercial source to the entity using such covered drugs." TMA's TPBP does not involve a federally owned and operated warehouse system, and, while it does involve a commercial warehouse system, that system does not have a direct contract with DoD. Nevertheless, prong (B) of the definition is broad enough to include the TMA plan. The commercial prime vendor or warehouseman serving the pharmacies can certainly be considered a commercial source, and the dispensing retail pharmacy fits within the description "entity using such covered drugs". This very broad language was most likely adopted by Congress to accommodate possible future pharmaceutical distribution techniques developed in this country and ultimately participated in by the Government. The TPBP is one such covered drug prescription distribution method.

2. Under TMA's plan, the acquisition of beneficiary prescriptions is a procurement by DoD. TPBP is a centralized system, i.e., "depot", for the acquisition, delivery, and distribution of prescriptions by DoD on behalf of its beneficiaries through the use of a DoD PBO and a contracted PBM with a retail pharmacy network. Additionally, DoD appropriated funds will be used by the PBO and PBM to pay for all TRICARE prescriptions and the PBM will be paid a negotiated administrative fee for performance of all services under the contract, including providing the retail pharmacy network and functioning as a fiscal intermediary for DoD. The PBM fee will not be related directly or indirectly to total pharmaceutical costs. The PBM will issue DoD appropriated funds (based on a letter of credit against a government account and authorized by the PBO) to pay for each TRICARE prescription, after receiving PBO's verification of the individual beneficiary's eligibility.

The filling of DoD beneficiary prescriptions at non-network retail pharmacies not under contract to the PBM would not qualify as a DoD procurement through a "centralized commodity management system," and therefore is not eligible for FCP.

3. VA has always believed that implied in the statute are the propositions that covered drugs purchased by the named Federal agencies at the statutory discount are not intended to provide the Government or its contractors with an opportunity to make a profit at the expense of drug manufacturers and are not intended to offer commercial health care organizations access to Federal pricing indirectly through the diversion of the discounted drugs to them for use in the commercial market. TMA's TPBP satisfies these implied statutory policies through the work of the proposed DoD PBO using a sophisticated Pharmacy Data Transaction System (PDTS) that will be linked to DEERS to ensure that non-DoD beneficiaries do not receive discounted prescriptions outside of TRICARE's parameters. The problem of possible diversion is almost completely eliminated because the TPBP would never put actual discounted drugs in the hands of a retail pharmacy. The latter would merely use its normal stocks of drugs, and DoD would receive the discount on the back end after its PBO submits utilization data to the manufacturers. Also, TPBP is not properly described as an insurance scheme because PBO software is used to approve prescriptions for every requesting beneficiary and DoD appropriated funds are used to pay for these prescriptions through PBM's efforts as agent of DoD. The only major difference between this model and the pharmaceutical supply contract/pharmaceutical prime vendor models that VA and DoD use for their own hospitals is that, under the TPBP, DoD requests a discount in the form of a rebate rather than up front at the time of the original purchase of the drug for the beneficiaries.

FACTUAL BACKGROUND:

Ever since DoD implemented its TRICARE program through the award of managed health care delivery contracts to civilian contractors for various regions of the United States in the mid-1990's, the office of DoD's Assistant Secretary for Health Affairs (OASHA) has been seeking to apply the pricing benefit of the P.L. to prescriptions filled for beneficiaries by commercial subcontractors of the TRICARE contractor. After an exchange of correspondence with DoD's OGC and a lengthy discussion within VA OGC as to the applicability of the P.L. to prescriptions filled through retail pharmacies as part of a capitated managed health care contract that was not strictly cost based, VA OGC published on October 7, 1996, a "Dear Manufacturer" letter containing guidance for manufacturers of covered drugs on several aspects of P.L. administration. The contents of the letter had been approved by the P.L. Policy Group.

Paragraph 3 of the letter to industry informed manufacturers of the interaction between VA and DoD concerning the possible eligibility of TRICARE contractors for FCPs. The "Dear Manufacturer" letter then stated:

> "An exchange of information between the Offices of General Counsel of DoD and VA has resulted in VA taking the position that the VHCA [P.L.] does not require manufacturers to make FCPs available to the presently awarded TRICARE contractors on orders placed by them or by their commercial pharmacy subcontractors for distribution through retail pharmacies. VA cannot conclude that such covered drug purchases under the TRICARE program, as presently structured, constitute covered drug procurements by the DoD within the wording of the act. Major factors in this conclusion are the absence of any direct DoD payment for invoiced pharmaceutical products and the lack of any way to trace pharmaceuticals purchased by a TRICARE contractor or subcontractor back to DoD on an item-by-item basis."

DoD reacted to VA's "Dear Manufacturer" letter by proposing that legislation be enacted to amend Title 10 of the United Stated Code to specifically bring the procurement of pharmaceuticals on behalf of DoD by an authorized contractor through an authorized retail pharmacy network or mail order program within the purview of 38 U.S.C. 8126. This proposal was never enacted into law, apparently as a result of industry's hostility to it when it was sent to Capitol Hill.

Subsequently, TMA, DoD OGC, and DoD OASHA representatives held discussions with counterparts from VA to discuss how FCPs could be obtained for the increasingly large TRICARE retail pharmacy expenditure. As an outgrowth of these discussions, TMA decided to carve the pharmacy benefit component out of its solicitations for the second round of regional TRICARE contracts and to create a DoD Pharmacy Benefit Office (PBO) that would be responsible for contracting with a commercial pharmacy benefits management firm (PBM) (and, through it, with a retail pharmacy network) which would serve as the PBO's agent for the procurement and dispensing of drugs for TRICARE beneficiaries outside of the military treatment facility system. This new approach was unveiled to VA in August 2001, and to industry in a general way at a pre-solicitation conference in September 2001. A description of the proposal, along with a diagram, was included in a letter from TMA's General Counsel to VA's Assistant General Counsel (025) on September 17, 2001.

The new TRICARE Pharmacy Benefit Program (TPBP) was considered by the VA Public Law Policy Group at its 2001 annual meeting, but questions were raised which required additional clarification. In November 2001, 025 wrote to TMA's General Counsel posing certain questions related to statutory interpretation and the practical operation of the TPBP. TMA answered these questions on February 12, 2002, at a meeting on April 23, 2002, and in a follow-up letter of June 28, 2002.

On September 24, 2002, the P.L. Policy Group reviewed all the correspondence and notes and concluded that TMA's interpretation of the P.L. as it applied to the TPBP was more reasonable than the opposing interpretation suggested by PhRMA.

DELEGATIONS WITHIN VA:

When VA was in the process of implementing the P.L. at the end of 1992 and the first half of 1993, there was a division of responsibilities. Since VHA's budget was the ultimate beneficiary of VA's participation in the statutory scheme, VHA's Drug and Pharmaceutical Product Management section (D&PPM) was given the responsibility of receiving and maintaining the annual reports of non-Federal Average Manufacturer Prices (Non-FAMP) for every covered drug that yield the FCPs for the following calendar year. On November 23, 1992, then Acting Secretary Principi signed a delegation to the Deputy Assistant Secretary for Acquisition and Materiel Management, giving him the authority to sign and administer Master and Pharmaceutical Pricing Agreements, with the authority to re-delegate as appropriate. On July 12, 2001, the Deputy Assistant Secretary for Acquisition and Materiel Management made a second re-delegation of his authority to the Assistant Director, Pharmaceutical, Dental and Other Schedules, Federal Supply Schedule Service at the VA National Acquisition Center. This delegation superseded all previous delegations including the original one to the Chief, Pharmaceutical Products Division at the NAC.

On July 29, 1993, Deputy Secretary Gober signed a delegation document giving the authority to receive and rule on discretionary FCP increase applications to an FCP Nominal Increase Board consisting of an OGC attorney (025), Chief, Drugs and Pharmaceutical Products Management (119), and a VA OIG Auditor chosen by the Director of Contract Audits (53C). Authority to hear and determine appeals from an adverse decision of that Board was delegated to the VA Board of Contract Appeals, whose decision shall be final. In the spirit of this delegation, the Public Law Policy Group was constituted by 025, the delegated administrative officials, and the Office of Inspector General (53C) to meet at least annually and reach collegial resolution of significant issues of administration arising under the statute. The Policy Group has met in September or early October of every year beginning in 1993 and has adopted almost all of its resolutions by consensus.

CONCLUSION:

For the above reasons, covered drugs purchased in the form of DoD beneficiary prescriptions under the retail portion of the new TPBP do qualify for Federal Ceiling Prices because, under the plan submitted to us, such purchases will be a procurement by DoD under a depot contracting system as defined in 38 U.S.C. 8126(h)(3).

DEPARTMENT OF VETERANS AFFAIRS
Office of General Counsel
Post Office Box 76
Hines IL 60141

December 30, 1992 Via Facsimile & U.S. Mail

In Reply Refer To: 025

Dear Manufacturer:

We have received your request for an increase in the Federal ceiling price of your pharmaceutical product pursuant to the requirements of the Veterans Health Care Act of 1992 (the "Act"). The Act at 38 U.S.C. 8126(a)(2) states that the price paid by the specified Federal agencies "...may nominally exceed..." the Federal ceiling price (FCP) "if found by the Secretary to be in the best interests of the Department or such Federal agencies". VA has determined that, in most instances, the statutory term "nominally exceed" does not allow any increase that exceeds 10% of the most recently reported annual non-FAMP.

In order to initiate the processing of a request for nominal increase in the Federal ceiling price, a manufacturer must submit a detailed written request justifying the increase for each separate covered drug item and a certification by its President stating that the FCP is below the production cost of that covered drug and selling at that price would cause the manufacturer to lose money on its overall business. The manufacturer also must agree to make full disclosure of relevant company records to enable VA to verify the accuracy of the certification (see enclosed certification).

Should the Secretary decide to grant the ceiling price increase, this amount will be added to the FCP. If the addition of the nominal amount does not result in a positive number, the ceiling price will be set at $.01.

Thank you for your cooperation with our efforts to implement the new Act. If you have any further questions, please do not hesitate to call (708) 216-2505.

Sincerely yours,

William E. Thomas, Jr.
Assistant General Counsel

CERTIFICATION

I, _____, (President of the company), hereby certify that I am the President of _____ (the Manufacturer), _____ (address) and that I have the authority to execute this certification for, and on behalf of _____ (Manufacturer). I certify that the current Federal ceiling price of (fill in name of product) is below the cost of producing this covered drug.

I certify that selling the above covered drug product to the Department of Veterans Affairs, Department of Defense, and Public Health Service, including the Indian Health Service at this price will cause _____ (Manufacturer) to lose money on its overall business.

I further certify that _____ (Manufacturer) I will make full disclosure of relevant financial records and that any representatives of the Government shall have the right to examine and audit any and all records and related documents necessary to verify the validity of my statements.

_____ _____

Signature Date

_____

Title

Merck & Co., Inc.
P. O. Box 1000
North Wales, PA 19454

2005-G501-8

VIA E-mail and FAX

June 11, 2005

Ms. Laurieann Duarte
General Services Administration
Regulatory Secretariat (VIR)
1800 F Street, N.W., Room 4035
Washington, D.C. 20405

Re: GSAR Case No. 2005-G501

Dear Ms. Duarte:

Merck & Co., Inc. ("Merck") appreciates the opportunity to comment on the above-referenced issued in the April 12, 2005, *Federal Register*. Merck is one of the largest manufacturers and suppliers of pharmaceuticals to the Federal government, in particular to the Department of Defense and the Department of Veterans Affairs. Merck recognizes and greatly values the sacrifices and contributions of our service members and is committed to help assure that they and their families (and all Americans) have access to necessary medicines and the highest quality health care. Further, Merck is sensitive to the budgetary constraints cited as a basis for the Proposed Rule, but believes that the most effective means to control healthcare costs (to include drug prices) is the competitive marketplace, not price controls. Merck opposes the Proposed Rule because we do not believe that it is the best way to make high quality healthcare available to DoD beneficiaries and because we have concerns about its legal underpinnings and implementation challenges. Therefore, we urge GSA to withdraw the Proposed Rule.

Merck does not believe that the Proposed Rule is consistent with Congressional intent under Section 603 of the Veterans Healthcare Act ("VHCA"). The legislative history shows that Congress intended to extend the Federal Ceiling Prices ("FCP") authorized by VHCA to pharmaceuticals procured by government through only two types of procurements: Federal Supply Schedule ("FSS") contracts and depot contracts. Congress did not intend – and VHCA does not authorize – the extension of FCP to other types of procurements or to those purchases that are not procurements, *e.g.*, reimbursements of prescription claims.

The Proposed Rule would establish a supplemental General Services Administration Regulation ("GSAR") concerning pharmacy benefit plans ("Federal Agency Retail Pharmacy Programs") of the "Big Four" agencies (VA, DoD, Public Health Service and the Coast Guard). Incorporation of the proposed supplemental GSAR into Federal Supply Classification ("FSC") Group 65 FSS contracts would require FSS holders (such as Merck) to pay "refunds" to the Big Four agencies on sales to beneficiaries of "covered drugs" dispensed through a qualifying Federal Agency Retail Pharmacy Program, collect and remit Industrial Funding Fees ("IFF") to VA, etc. Importantly, the transactions underlying the "refund" requirement are not procurements by a Big Four agency. Rather, the underlying transactions involve a retail pharmacy's purchase of a pharmaceutical product from a commercial source, followed by the sale of the product at a negotiated price to a beneficiary. Title passes from the commercial source to the retail pharmacy to the beneficiary; the Federal government never takes title or possession of the product. Federal dollars are introduced in the form of reimbursements. Merck does not believe that the

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retrospective introduction of federal dollars is sufficient to transform a commercial purchase into an authorized FSS order or creates a "virtual depot contracting system" to which Merck is a party.

A second defect with the Proposed Rule is that it appears to be outside GSA's statutory authority. Because VA is responsible for interpreting the VHCA, to the extent that the proposed rules involve substantive interpretation of the VHCA, VA (not GSA) should publish rules for notice and comment.

In addition, Merck believes that the Proposed Rule is ambiguous (which could cause significant operational difficulties) and imposes numerous additional record-keeping/reporting requirements. If the Proposed Rule is not withdrawn, Merck respectfully requests that GSA clarify or reconsider several elements of the Proposed Rule, to include the following:

(1) Contract Modifications. The Proposed Rule is silent concerning the method by which the new clause would be incorporated into FSS contracts. FSS contracts include provisions stating that changes its terms and conditions may be made changed only by written agreement of the parties. Merck requests GSA to clarify the Proposed Rule to reflect that modifications to current FSS contracts will require written agreement of the parties.

(2) Refund Calculations. Under the proposed clause, refunds would be calculated quarterly based on the difference between a benchmark price (either the actual sales price to the wholesaler or retail pharmacy chain if known and auditable or the non-FAMP) and the FSS price or FCP, whichever is lower. However:

(a) The Proposed Rule does not specify whether the Federal agency or the contract holder would determine the benchmark price to be used. Merck urges that this should be contract holder's decision, because the contract holder is in the best position to know the prices that it receives for its products from wholesalers or retail pharmacy chains.

(b) The phrase "...if known and auditable..." is unclear as is the term "retail pharmacy chain." Merck respectfully requests clarification of these terms.

(c) The Proposed Rule does not appear to address the importance of prospective identification of retail pharmacies comprising the network pharmacy. Such identification is essential so as to ensure that "refunds" are properly calculated (e.g., claims from ineligible pharmacies, etc. are excluded).

(c) The proposed "refund" formula does not adjust potential differences between the package size (on which FCP is based) and the quantities of a covered drug that are considered in calculating the actual sales price (dispensed units, etc.).

(d) The Proposed Rule is unclear with regard to several aspects of non-FAMP calculations to include whether direct sales to retail pharmacies may (or must) be included in non-FAMP calculations or whether utilization data may be handled in the non-FAMP calculation on a "cash" basis based on the date that a manufacturer pays a "refund."

(e) The Proposed Rule does not address the methodologies to be employed in situations where a product has been discontinued or when the patent covering a branded product has expired. With regard to the former, failure to synchronize multiple report dates could result in situations where the "refund" reporting period would extend beyond the period for which a non-FAMP was calculated.

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(f) The Proposed Rule contemplates that a Federal agency administering a retail pharmacy program would provide utilization flat file layout reports to FSS contract holders on the 15th day of the first month after the close of a calendar quarter. The manufacturer would then have 70 days to calculate the "refund" amount owed, reconcile the calculation with the Federal agency calculation, and pay the "refund." Thus, the refund amount would be due 85 days after the close of each calendar quarter. Additionally, the proposed clause would require FSS contract holders to report retail pharmacy sales and pay the IFF within 60 days of the close of the quarter. At a minimum, the schedules in the two clauses should be reconciled so that IFF payments are not due on retail pharmacy sales until the later of 70 days after the contract holder's receipt of full utilization flat file layout reports or 85 days after the end of each calendar quarter.

(g) Disputes. The Proposed Rule would require the contract holder to pay the refund according to the agency's calculation (including the disputed amount) and then use "best good faith efforts" to resolve the dispute within 60 days. This approach is inconsistent with the Contracts Dispute Act and with best business practices. Merck urges revision of the dispute resolution process to include a requirement for good faith negotiations coupled with a manufacturer's payment of only that portion of the "refund" that is not disputed and to pay any balance plus interest by the due date of the next quarterly payment after the dispute is resolved. In addition, Merck urges revision of the dispute resolution process to impose similar obligations on Government parties [e.g., requiring remittance of IFF payments (with interest) or remittance of overpayments (with interest) if good faith negotiations or a court decision subsequently result in a reimbursement of part of the refund to the contractor].

The Proposed Rule seems to suggest that (a) a manufacturer's costs, time and effort required to comply with the Proposed Rule is minimal; and (b) there are no alternative mechanisms whereby DoD could decrease its pharmaceutical costs in the retail pharmacy sector. Merck respectfully disagrees with both of these suggestions. The effort required to calculate and pay "refunds" is not "essentially clerical"; rather, evaluating and processing of thousands of transactions in compliance with multiple statutes requires significant advanced professional skills and additional computer capability and capacity. Further, the business practices of the private sector – which include the use of pharmacy benefits managers and expanded use of mail-order pharmacies – are two of many cost-effective alternatives that are readily available. It is noteworthy that a mail-order pharmacy is an existing component of DoD TRICARE health system, the TRICARE Mail Order Pharmacy ("TMOP"). For TRICARE beneficiaries, TMOP is a cost-effective alternative to the retail pharmacy: a beneficiary pays $3, $9 or $22 cost-share for a 30-day supply of drugs in the retail pharmacy setting; in contrast, a beneficiary pays the same $3, $9 or $22 cost-share for a 90-day supply of drugs for purchases made from the TMOP.

Merck appreciates your consideration of these comments. We remain committed to working with DoD, VA and others in the Federal government to develop alternatives that can accommodate the concerns raised by all parties in a manner that is consistent with existing laws. As we strongly believe that the Proposed Rule is not authorized under law and would have detrimental policy and implementation consequences, we urge its withdrawal.

Sincerely,

/S/
C. E. Carty
Senior Attorney

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The Coalition
for Government
Procurement

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June 9, 2005

Ms. Lauriann Duarte
FAR Secretariat
General Services Administration
1800 F Street, NW
Room 4035
Washington, D.C. 20405

RE: GSAR Case 2005-G501

Dear Ms. Duarte:

The Coalition for Government Procurement is pleased to have this opportunity to submit comments on the above-referenced proposed rule issued in the April 12, 2005, *Federal Register*. The Coalition strongly opposes the proposed rule.

The Coalition is a multi-industry association of government contractors. We have over 330 members representing all commercial item market segments. Our members account for over 70% of the sales made through the Multiple Award Schedules program and about half of all commercial sales made annually to the federal government. Included in our membership is nearly every major pharmaceutical company selling through the VA Federal Supply Schedule program.

The Coalition has worked *with* officials in government for over 25 years for common sense acquisition rules. Specifically, we have worked with representative of GSA, the VA, DOD, OMB, and Congress over the ability of the DOD Tricare TRRx retail pharmacy program to have access to federal ceiling prices on pharmaceuticals for nearly three years. This is the issue covered by the proposed rule. We believe this proposal put forth by GSA is an attempt to implement via regulation a scheme that the VA and DOD have not been able to implement otherwise.

<u>INTERPRETATION CONCERNS</u>

We disagree that the proposed clause is consistent with Congressional intent under Section 603 of the Veterans Healthcare Act (VHCA) in the strongest possible terms. The Coalition has a long history of working with this statute

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and has had substantial opportunity to review the legislative history surrounding it. We believe strongly that this record shows that Congress did not intend to extend federal ceiling prices to pharmaceuticals the government, itself, never purchases.

The proposed rule covers pharmacy benefit plans of the "big four agencies" (VA, the Department of Defense, Public Health Service and the Coast Guard) that are structured as follows: the agency contracts with a pharmacy benefit manufacturer to act as its fiduciary agent and use government funds to pay a share of it network retail pharmacies' charges for prescriptions ordered by the plan beneficiaries in accordance with a predetermined cost-sharing formula. The proposed rule would require inclusion of a special clause that would deem prescription orders of medication units places by beneficiaries with retail pharmacies to be orders of federal agencies from manufacturers under their FSS contracts, while eliminating the contractors' rights under FAR 52.216-18, 52. 216-19 See 552.238-XX.

The rule mischaracterizes the transactions that occur at the pharmacy as "instructions to fill the prescriptions." The Pharmacy Benefit Manger (PBM) merely tells the pharmacy whether the beneficiary's federal plan will pay for it and how much. In fact, a prescription is an order from a physician to dispense drugs to a patient, and only the patient or a health care professional can order a pharmacy to fill a prescription. The decision on whether to fill the prescription at all, whether to fill it as written, or whether to substitute an equivalent drug is that of the beneficiary, not the agency or its fiscal intermediary. The agency and the PBM can only control whether the government or the beneficiary will pay for the prescription order and how much of the pharmacy charge will be shared.

In addition, the proposed rule ignores the fact that the retail pharmacy is the owner and source of the drug ordered and delivered to the beneficiary, and unlike procurements from the agency's prime vendor, there is no procurement contract with the retail pharmacy under which it promises to act as a conduit and sell goods to the government at the FSS price. In this construct, although the retail pharmacy receives the prescription order, fills it with product from its commercial stock, and is paid for it, it is not treated as the vendor from which FSS line items are sourced, but rather a "deemed" purchasing agent of the government.

The Coalition is concerned with this line of reasoning implicitly taken by GSA in the proposed rule. The pharmacy does not purchase the dispensed units ordered by the beneficiaries from manufacturers under the FSS contracts pursuant to a contract with the agency. It buys drugs from commercial sources, takes title, and uses them in its business, charging a negotiated price for dispensed units unrelated to the FSS contract price. Were it truly a purchasing agent, it would be contractually required to pass on the FSS contract price. Nor is the pharmacy a cost "subcontractor" entitled to buy off the FSS under existing FAR rules because it is not paid its acquisition cost plus a fixed fee for drugs used by the prime in performance of a government contract and is not subject to procurement rules applicable to cost contracts. A specific statute is necessary to mandate these particular FSS contractors pretend retail pharmacy sales of

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medications they manufacture are indirectly ordered from them on behalf of particular government agencies. Even the prime vendor program requires manufacturer consent.

The proposed rule forces certain FSS contractors, manufacturers of covered drugs, to agree as a condition of selling their products on the Federal Supply Schedule to the following contract term: approval by a fiscal intermediary of select agencies to pay one of its network health care providers a share of the provider's charge for an order placed by an agency program beneficiary shall be "deemed" an order by the agency from the manufacturer "through" the provider under the FSS contract, thereby granting the agency a contractual right to the contract price from the manufacturer on these third party payment transactions. Imposing these legal obligations on certain FSS contractors through the terms of their FSS contracts is unprecedented and unauthorized by any statute.

The Coalition also feels that the proposed rule is not clear in the statutory source of authority for granting the big four agencies the special contract rights contemplated, i.e., whether GSA's own statutes or the VHCA authorizes GSA to amend the GSAR in this manner. It is our belief that the applicable rules and statutes do not provide this authority. We are particularly concerned that the scope of the proposed rule is not limited to statutory ceiling prices available to the big four, but would require VA FSS contractors to extend their negotiated prices to particular federal program beneficiaries.

The Master Agreement and the pricing agreement required by the VHCA provide that actual contract prices are to be negotiated in good faith within the prescribed framework of the FAR, GSAR, VA acquisition regulations and other applicable rules. The FCP is merely a cap on those prices for the four agencies that procure pharmaceuticals for use in providing treatment at their facilities. The Coalition does not believe that GSA has the statutory authority to change the GSAR to grant select agencies special contract rights with respect to certain products of certain contractors under FSS contract rules and to read out rights to order limitations provided by the FAR. We know of no law that would permit GSA to "deem" the following: an order placed by a beneficiary is an order placed by an agency; an order placed with a retailer is an order placed with the contractor, and an order placed for medication units that are not described in the contract CLIN structure is an order of product units offered for sale by manufacturers under the contract.

We also believe that there is no authority to alter the bargain struck with respect to the negotiated terms of the contract. When manufacturers of covered drugs offer sub-ceiling prices under the FSS, the contracts are treated the same as all other FSS contracts for goods. Clearly, the VHCA does not deal with virtual depot contracting systems because, prior to the current effort to expand the original intention of the Act, there was no such concept. There is nothing in the VHCA that compels manufacturers to extend FSS prices to depot contracting systems.

An additional Coalition concern is that the proposed rule, itself, is inconsistent with GSA's own precedent setting determinations on schedule eligibility. The agency has previously, and

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consistently, rejected eligibility claims made on criteria to those substantially the same as those now put forth in the proposed rule. We believe strongly that the transactions between beneficiaries and retail pharmacies are not procurements. Rather, they are more closely identified as an agency or other entity receiving federal funds under a Cooperative Agreement, grant, loan, or other subsidy.

GSA has repeatedly rejected the interpretation that such transactions are procurements because the government can only use a procurement contract to pay for goods that are acquired for its own use. There is no procurement here. The transactions are payments by a fiscal intermediary reimbursing a retail pharmacy a cost share for providing a prescription to a beneficiary and have the same purpose as if the fiscal intermediary reimbursed the beneficiary who received the prescription the same amount if he or she paid the whole charge.

The Coalition believes that the nature of the transaction is that of a subsidy or insurance payment, which the FAR recognizes as a non-procurement transaction. See FAR 9.403. This distinction is similar to the difference between a voucher to obtain goods or services in the private sector and a procurement. A pharmacy dispensing a prescription to a Tricare beneficiary paid in part by DOD is no more ordering drugs for the Government than a landlord is leasing to the Government when HUD pays it a rental subsidy, or a retail grocer is ordering food for the Government when it accepts food stamps redeemed by DOA, or a private school is educating the Government when it accepts a tuition voucher from the student. In each of these cases the Government can choose to meet the health care, housing, educational or nutritional needs of its beneficiaries by directly providing them, in which case it can procure goods it needs to function as a provider (e.g., build and rent out low cost housing or buy and distribute

Case law supports an interpretation of the Tricare system as an assistance program rather than a procurement contract. For example, in *Partridge v. Reich*, a county fire department receiving federal funds under a contract between the Federal Emergency Management Agency ("FEMA") and the State allegedly violated the Veterans Readjustment Assistance Act ("VEVRA"), which required procurement contractors to implement affirmative action plans for veterans. The court determined that VEVRA did not apply to all agreements between the Federal government and third parties, but only to contracts for "procurement" for personal property and services for use by the government, concluding that an agreement to pay for emergency service between FEMA and the State was not a contract for "procurement" of services by FEMA. Likewise, the statutes authorizing GSA to execute procurement contracts with manufacturers do not extend to expenditures of federal funds for their products under non-procurement agreements.

In this case, DOD is making financial assistance payments to civilian pharmacies for prescriptions acquired not by DOD—which does not have a legal right to the dispensed drugs but by Tricare beneficiaries. There is no direct use by or for the Government, as required by the FAR. Accordingly, reimbursement of prescription claims is not a procurement of drugs by DOD.

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By implementation of the Uniform Formulary multi-tiered structure in April 2004, the DOD moved toward creating a situation where pharmaceutical manufacturers were competitively incentivized to offer the agency more favorable pricing to achieve optimal formulary status. This is consistent with the best practices commercial model and the intent of the Congress. By the government setting prices through this proposed rule and a rebate mechanism it has effectively removed the market incentives to control costs. The Coalition feels that this is not in the government's best long-term interest.

On a final point in this area, the Coalition wishes to point out that throughout the government's attempts to expand the authority of the VHCA to include TRICARE retail pharmaceutical sales, the terms ***"rebate"*** and ***"discount"*** have been used interchangeably as if they were synonymous. This is not the case. A ***"discount"*** is an upfront reduction in purchase price normally based on favorable trade terms or preferred customer status. The Federal Ceiling Price described in the section 603 of the VHCA is a ***"discounted"*** price. A ***"rebate,"*** however, is a backend return of a proportion of the original purchase price usually based on volume of sales. The VHCA does not authorize or discuss ***"rebates."*** However, ***"rebates"*** are what are being proposed by this GSA rule.

OPENING THE SCHEDULE TO BENEFICIARIES

The proposed rule deems orders of supplies by federal beneficiaries placed with retailers for the personal use of the beneficiaries to be orders from the schedule contractors. Yet, neither beneficiaries nor retailers are authorized users of the schedule contracts. By authorizing indirect use through "deemed orders," the proposed rule authorizes use by entities that could not place orders directly. The Coalition does not believe that the VHCA authorizes this scheme. Similarly, we do not believe that the laws and regulations governing the Multiple Award Schedules program allow for these types of procurements. As such, the Coalition believes that the proposed rule is fundamentally incompatible with the intent of the schedules program. Taken to its next step, GSA could just as easily open up the MAS program to deemed orders by grantees, loan recipients, or others entitled to have federal agency funds pay for goods.

We see this as a very dangerous precedent that would undoubtedly have a substantial and deleterious impact on the government's largest commercial item procurement method. The ramifications of this potential are huge. We strongly recommend steering away from this course as the agency reconfigures itself and continues to respond to criticism that some customers already make improper use of GSA contracts.

IMPACT ON OFPP ACT

The Office of Federal Procurement Policy Act (OFPPA) incorporates the Chiles Act, 31 U.S.C. 6303-6305, which prohibits agencies from using procurement contracts for transactions when the purpose is the acquisition of supplies for the benefit and use of parties other than the Government. That is why we have grants, cooperative agreements, assistance agreements, and other transactions. Here, the drugs are not entirely paid for by the agency and they are not being used by the agency. It is contrary to law and federal procurement policy to allow GSA to use the FSS to cover assistance transactions.

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IMPLEMENTATION CONCERNS

Aside from the fact that there is no statutory authority for this proposal, the Coalition is also very concerned over the manner in which GSA would implement the proposed regulatory change, even if some heretofore unknown authority does exist, on established contracts already in existence. Certainly the change contemplated by the proposed rule greatly alters current contracts. Even if GSA has the discretion to insert new clauses in new contracts and solicitations, without clear statutory authority to impose such new obligations on the contractors during the base term, the proposed rule's clause will be a cardinal change. We see no alternative other than negotiating brand new contracts based on this new reality with every pharmaceutical contractor and ending all current contracts. This would be a very substantial undertaking as the contracts currently in place took several years to negotiate and award.

We see this as a substantial burden to contractors, especially small businesses. It does not seem that this impact was adequately assessed in the *Federal Register* notice. We request that an appropriate small business impact statement be prepared before any formal rule goes forward and that the comment period be extended to allow small firms adequate opportunity to comment on the resultant findings.

CONCLUSION

The Coalition believes that the proposed rule is not in the best interest of government, industry, or Tricare beneficiaries. We believe it is essentially a political attempt to provide coverage for a program badly wanted by DOD to meet now-expected budget parameters, but which fails to pass regulatory or statutory muster. It simply does not provide adequate, or in our view legitimate, legal justification to achieve the desired end. We urge the withdrawal of the rule and recommend that DOD and the VA seek other means to achieve their end in cooperation with their industry partners.

Sincerely,

Larry Allen
Executive Vice President

2005-G501-7

PhRMA

June 13, 2005

BY HAND DELIVERY

Ms. Laurieann Duarte
General Services Administration
Regulatory Secretariat (VIR)
1800 F Street, N.W., Room 4035
Washington, D.C. 20405

Re: GSAR Case No. 2005-G501

Dear Ms. Duarte:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to comment on the Proposed Rule published by the General Services Administration ("GSA") on April 12, 2005.[1] PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA recognizes the extraordinary sacrifices made by the men and women of our military and is committed to doing its part to assure that they have access to the best possible medicines and the highest quality health care. We offer these comments because we do not believe the Proposed Rule is the best way to achieve our mutual objective of making available the best quality care to our military personnel and their dependents. Additionally, we believe that the underpinnings of the Proposed Rule are not sound.

The Proposed Rule would establish a supplemental General Services Administration Regulation ("GSAR") clause, entitled "Federal Agency Retail Pharmacy Program Supply Schedule," that could be incorporated into the Federal Supply Classification ("FSC") Group 65 Federal Supply Schedule ("FSS") contracts. This new clause would permit the Department of Defense ("DoD"), the Department of Veterans Affairs ("VA"), the Coast Guard, and the Public Health Service ("PHS") (collectively, "the Big Four") to obtain rebates, referred to in the Proposed Rule as "refunds," from FSS contractors on sales of "covered drugs" dispensed through a qualifying "Federal Agency Retail Pharmacy Program." The clause also would require FSS contract holders to report qualifying retail pharmacy sales to the VA and allow the VA to collect an Industrial Funding Fee ("IFF") on those sales. The clause would not affect the amount

[1] 70 Fed. Reg. 19,045 (Apr. 12, 2005).

that beneficiaries of the TRICARE health system (or any other health system) would pay for their prescriptions.[2] Nor would it increase, improve, or affect beneficiary access to medicines.

The Proposed Rule should be withdrawn for two general reasons:

(1) The GSA lacks statutory authority to implement the Proposed Rule; and

(2) The Proposed Rule would create significant operational problems for both the VA and FSS contract holders.

The most effective means to meet the budget objectives cited as the basis for the Proposed Rule is the competitive marketplace, not the extension of price controls or other artificial price constraints or price ceilings as the Proposed Rule contemplates.[3] The commercial sector employs several types of market-based approaches, including competitive negotiations.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), passed by Congress and signed into law by President Bush on December 8, 2003, establishes a market-based approach for managing the new prescription drug benefit for the more than 40 million Americans who are enrolled in the Medicare program.[4] In our view, a similar market-based solution would work well for the DoD and the VA in their efforts to develop a retail pharmacy benefit, where the government's role is as a third-party payer as opposed to a direct provider of the prescription drugs that are dispensed to its beneficiaries. And, unlike with the approach set forth in the Proposed

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[2] The cost shares paid by TRICARE beneficiaries are defined in a Uniform Formulary Rule issued on April 1, 2004. *See* 69 Fed. Reg. 17,035 (Apr. 1, 2004).

[3] Indeed, prior government reports have suggested that making FSS pricing available to the private sector would have unintended adverse consequences for the prices for other health benefit plans. *See, e.g.*, Gen. Accounting Off., Pub. No. GAO/HEHS-00-118, Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes (Aug. 7, 2000).

[4] Among other provisions, the MMA requires that there must be at least two approved prescription drug plans per Medicare region from which beneficiaries may choose and that each drug formulary must contain at least two drugs per therapeutic class. MMA, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

Rule, we are not aware of any statutory or regulatory impediments to the development of market-based approaches to cost containment by either the DoD or the VA.[5]

For the reasons stated in this letter, the GSA should withdraw the Proposed Rule and encourage the DoD, the VA, and other Federal agencies to pursue market-based solutions as alternatives to the "refund" process that the Proposed Rule contemplates.

I. The Proposed Rule Is Not Authorized by Law

A. The GSA is Not Authorized to Promulgate the Proposed Rule

The principal defect with the Proposed Rule is that it is outside of the GSA's statutory authority. Accordingly, we believe that the GSA's promulgation of the rule would be an ultra vires agency action. It also would be fundamentally at odds with one of the five major objectives of the GSA's "Get it Right" plan to: "ensure compliance with federal acquisition policies, regulations and procedures."[6]

The preamble to the Proposed Rule does not specify the statute or statutes under which the rule would be issued or explain how the Proposed Rule itself would be consistent with Congressional intent. However, the preamble and the rule reference three statutes that the GSA apparently believes support parts or all of the Proposed Rule: (1) Section 603 of the Veterans Health Care Act of 1992 ("VHCA"), 38 U.S.C. § 8126; (2) Sections 201(a) and 309 of the Federal Property and Administrative Services Act ("FPASA"), 40 U.S.C. § 501 and 41 U.S.C. § 259(b); and (3) the National Defense Authorization Acts of 1999 and 2000, 10 U.S.C. § 1074g. None of these statutes contemplates the rule under consideration.

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[5] As explained in section I.A.3 below, use of a market-based solution would be consistent with the Congressional requirement that DoD adopt "the best business practices of the private sector" in establishing an integrated and uniform health benefit for its beneficiaries. *See* 10 U.S.C. § 1074g(a) (2004).

[6] *See* Gen. Servs. Admin., Get It Right: A Comprehensive, Governmentwide Approach at 7, *available at* http://www.gsa.gov/gsa/cm_attachments/GSA_DOCUMENT/GIRight%20_org_pre-R2_iP1B_0Z5RDZ-i34K-pR.ppt/269

1. The Veterans Health Care Act of 1992, 38 U.S.C. § 8126

Summary of the VHCA. In relevant part, the VHCA requires manufacturers of "covered drugs" to enter into Master Agreements and Pharmaceutical Pricing Agreements ("PPAs")[7] with the VA under which manufacturers agree to make a statutorily-mandated discount, known as the Federal Ceiling Price ("FCP"), available to the Big Four agencies for all of the manufacturer's covered drugs that are "purchased under depot contracting systems or listed on the Federal Supply Schedule."[8] The VHCA defines the term "depot" as:

> a centralized commodity management system through which covered drugs procured by an agency of the Federal Government are –
>
> (A) received, stored, and delivered through –
>
> (i) a federally owned and operated warehouse system, or
>
> (ii) a commercial entity operating under contract with such agency; or
>
> (B) delivered directly from the commercial source to the entity using such covered drugs.[9]

The Proposed Rule concludes that a Federal Agency Retail Pharmacy Program would qualify for Federal pricing because it would constitute a "virtual" depot contracting system, but does not articulate the statutory basis for this conclusion.[10] Indeed, as described below, this conclusion lacks statutory support.

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[7] If a manufacturer does not have an executed Master Agreement and PPA, then it may not receive payment for purchases under Medicaid and other programs. *See* 38 U.S.C. § 8126(a)(4).

[8] *Id.* § 8126(a)(2).

[9] *Id.* § 8126(h)(3).

[10] 70 Fed. Reg. at 19,050 (Subsection (c)(2) of the proposed clause notes that a Federal Agency Retail Pharmacy Program is a "virtual depot system").

The VHCA Is Narrow in Scope. Congress intended for the VHCA to have a limited application. Both the Senate and the House Committee Reports relating to the VHCA recognized the four means by which the VA and DoD procured drugs (FSS contracts, a depot system, a single award contract and open market purchases)[11] and extended the FCP to procurements made through only the first two of those methods. Congress did not reference DoD reimbursement for drugs dispensed under the CHAMPUS program (the TRICARE predecessor civilian health insurance program), thus demonstrating Congress' intent that the FCP should not apply to government reimbursement programs, such as a retail pharmacy program.[12]

The VA has previously construed the VHCA consistent with Congress' intent. Until recently, the VA defined the term "depot" to include only "centralized commodity management systems through which covered drugs are: (A) received, stored and delivered to a listed federal agency through a federally-owned warehouse system or a commercial warehouse system operating under contract with the procuring federal agency; or (B) delivered directly from the manufacturer or its agent to a listed federal agency's ordering activity at its purchasing address."[13] Neither of the definitions that the VA previously used would encompass a Federal Agency Retail Pharmacy Program where there is no procurement contract between the drug manufacturer and the government or the government's purchasing agent. Furthermore, the VA expressly concluded in 1994 that the VHCA "does not require manufacturers to grant the discount to . . . government contractors authorized to use the FSS" and specifically characterized the VHCA as imposing a "limited" discount.[14] These statements are directly at odds with the

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[11] S. Rep. No. 102-401, at 62-63 (1992); H.R. Rep. No. 102-384 (I), at 4 (1991).

[12] In promulgating the VHCA, Congress understood the important distinction between the government as a third party payer and the government as a direct purchaser of drugs, and understood that the latter could result in a depot contracting system whereas the former could not. *See* S. Rep. 102-228(I), DEVELOPMENTS IN AGING: 1990-VOLUME 1, 1991 WL 52579 at *254 (Mar. 22, 1991) (recognizing that depot prices are excluded from best price calculation under the Medicaid Rebate statute because "depot prices reflect the manufacturer's costs of delivering the product in bulk to a provider, without packaging costs" and that, because "Medicaid is a reimbursement system, not a direct purchaser of drugs," it would be "unfair for Medicaid to have access to prices that are determined based on this mode of distribution.").

[13] Letter from Phillipa L. Anderson, Assistant General Counsel, Dep't of Veterans Affairs, to Robert D. Seaman, General Counsel of TRICARE Management Activity (Nov. 1, 2001). (Attached as Exhibit A).

[14] Letter from William E. Thomas, Jr., Assistant General Counsel, Dep't of Veterans Affairs, to Lt. Col. Henry L. Smith, OASD (HA) HSF/MCO, the Pentagon 1 (July 28, 1994). (Attached as Exhibit B).

unprecedented interpretation of "depot" that underlies the Proposed Rule's conclusion that a retail pharmacy program qualifies as a depot contracting system.[15]

The DoD has also previously recognized that the VHCA does not authorize agencies to apply the FCP to retail pharmacy sales. Following a 1996 VA letter to covered drug manufacturers rejecting a DoD request to apply the VHCA to TRICARE network retail pharmacies, the DoD expressly sought legislation "to specifically bring the procurement of pharmaceuticals on behalf of DoD by an authorized contractor through an authorized retail pharmacy or mail order program within the purview of 38 U.S.C. § 8126."[16] Congress did not change the law in response to the DoD's request. The DoD's decision to seek such legislation confirms the DoD's understanding that the VHCA did not then, and therefore does not now, extend to retail pharmacy sales.[17]

The Proposed Rule Conflicts with the VHCA Definition of "Depot." Notwithstanding Congress' intent that the VHCA apply only to Federal procurements of covered drugs and the VA and DoD's prior interpretation of the VHCA, the preamble to the Proposed Rule concludes that: "[t]his rulemaking is consistent with the authority provided by 38 U.S.C. § 8126 to acquire drugs at the statutorily provided discount through use of a depot contracting system."[18] PhRMA respectfully disagrees. As the VA previously concluded, the term "depot" in the VHCA does not extend to retail pharmacy programs and does not apply to "virtual" depot contracting systems. The definition of "depot" in the VHCA specifically requires a "centralized commodity management system" through which covered drugs are "procured" by an agency of the Federal government. The term "procurement" has a well-established meaning: it refers to the

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[15] In October 2004, the VA announced to covered drug manufacturers that DoD's TRICARE Retail Pharmacy ("TRRx") Program complied with the VHCA because the retail pharmacy benefit as structured was a "virtual" depot contracting system. Letter from Steven Thomas, Acting Executive Director, VA National Acquisition Center, to Manufacturer of Covered Drugs (Oct. 14, 2004). (Attached as Exhibit C). However, the VA did not explain the basis for this conclusion or explain why its interpretation of the VHCA changed.

[16] White Paper for the Office of the Secretary: TRICARE and Federal Ceiling Prices at 4 (Oct. 10, 2002). (Attached as Exhibit D).

[17] *Id.*

[18] 70 Fed. Reg. at 19,046.

acquisition of goods and services with appropriated funds for the government's benefit or use.[19]

The drugs that would be dispensed through a Federal Agency Retail Pharmacy Program are not "procured" by a Federal agency. Instead, the retail pharmacy would procure the drugs through its contracts with commercial wholesalers or manufacturers, and the program beneficiary in turn would procure the drugs from the retail pharmacy. The Federal government would never take title to or possession of the drugs. There would be no procurement contract under which drug manufacturers agree to provide the covered drugs in question to the Federal government or a vendor or agent of the Federal government.[20] Nor would there be any contract under which manufacturers agree to make the FSS (or FCP) available for the drugs that are dispensed through retail pharmacy programs. The government's sole role in the retail pharmacy transaction would be to authorize the pharmacy to fill the prescription and to reimburse the pharmacy (after the fact) for the government's share of the retail price.[21] Because there would be no Federal procurement of the drugs that are involved in this transaction, a Federal Agency Retail Pharmacy Program would not qualify as a depot contracting system under the VHCA.

The Proposed Rule Does Not Explain Why a Federal Agency Retail Pharmacy Program Would Qualify as a Depot Contracting System. As noted, contrary to prior determinations, the Proposed Rule concludes without explanation that the Federal Agency Retail Pharmacy Program procedures established in the proposed clause "are consistent with 38 U.S.C. § 8126."[22] The GSA must specify the basis for this

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[19] *See* 41 U.S.C. § 403 (2003); 48 C.F.R. § 2.101 (2005). *See also Appeal of Mayer*, HUDBCA No. 83-823-C20, 84-2 BCA ¶ 17,494 (1984) ("acquisition by purchase, lease, or barter, of property [or] services *for the direct benefit or use* of the Federal Government ... characterizes a Federal procurement.") (emphasis added).

[20] Retail pharmacies are not prime vendors or purchasing agents of the Federal government.

[21] Both the Federal Acquisition Regulations ("FAR") and the VA rules include insurance transactions and subsidies, such as a Federal Agency Retail Pharmacy Program, within the definition of "nonprocurement transactions." FAR § 9.403 (2005); 38 C.F.R. § 44.970 (2005).

[22] 70 Fed. Reg. at 19,050.

conclusion.[23] In particular, the GSA does not specify the part of the VHCA definition of "depot" that authorizes a Federal Agency Retail Pharmacy Program. If the GSA believes that the second alternative definition of depot (*i.e.*, direct delivery of the covered drugs from a commercial source to the entity using the covered drugs) supports this conclusion, then, at a minimum, the GSA must identify the entities that it believes constitute the commercial source and the end user of the covered drugs that would pass through the Federal Agency Retail Pharmacy Program.

Likewise, the Proposed Rule does not specify the contractual basis for its apparent conclusion that a Federal Agency Retail Pharmacy Program involves a Federal procurement. For example, the Proposed Rule does not identify any procurement contract under which a manufacturer agrees to sell the covered drugs that would be dispensed through the retail pharmacy program to a Federal agency or an authorized purchasing agent for the Federal price. Nor does the Proposed Rule identify a contract between a Federal agency (or its pharmacy benefit manager) and the retail pharmacies under which the retail pharmacies agree to act as a purchasing agent or prime vendor for the Federal agency. Such contracts would be prerequisites to a Federal procurement, which in turn is a prerequisite to a depot contracting system under the VHCA. PhRMA respectfully requests a full explanation of the basis for the Proposed Rule's conclusion that a Federal Agency Retail Pharmacy Program, if compliant with the procedures set forth in the proposed clause, would qualify as a depot under the VHCA.

The GSA Lacks Authority To Interpret the VHCA. The GSA, and not the VA, issued the Proposed Rule that purports to interpret the VHCA. While the VA did issue a letter to covered drug manufacturers in October 2004 that ostensibly authorized the DoD's TRICARE Retail Pharmacy Benefit ("TRRx") Program, that letter was not published for notice and comment.[24] Moreover, the VA, and not the GSA, is responsible

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[23] *PG&E Transmission, Northwest Corp. v. Fed. Energy Regulatory Comm.*, 315 F.3d 383, 386 (D.C. Cir. 2003) (Agency must be able to demonstrate that it has made a reasoned decision based upon substantial evidence in the record and articulate a satisfactory explanation for its actions including a rational connection between the facts found and the choice made.).

[24] 5 U.S.C. § 553.

for interpreting the VHCA.[25] The VA, and not the GSA, should publish rules for notice and comment to the extent that those rules are premised on a substantive interpretation of the VHCA.. The GSA interpretations of the VHCA are not entitled to legal deference.

The VHCA Does Not Authorize Federal Agencies To Obtain FSS Pricing. Independent of the Master Agreement and PPA mandated by the VHCA, manufacturers and the VA also establish FSS prices for drugs sold under the FSS contracts. FSS prices are developed pursuant to the terms and conditions of the FSS contract solicitations.[26] As the Proposed Rule acknowledges, the FSS price for a drug can be lower than the drug's FCP.[27] The VHCA does not authorize Federal agencies to access FSS prices for their depot contracts. Nor does the VHCA permit Federal agencies to collect rebates from manufacturers. Instead, as noted, the VHCA only allows the Big Four agencies to acquire covered drugs through a depot contracting system at a statutorily-mandated discounted price that is no higher than the FCP (not the FSS). To the extent that the VHCA is cited as support for the payment of rebates designed to approximate FSS pricing, the clause would thus be invalid. The GSA should clarify that it is not relying on the VHCA for its proposal to require payment of rebates based on the FSS prices for retail pharmacy purchases.

2. The Federal Property and Administrative Services Act ("FPASA"), 40 U.S.C. § 501 and 41 U.S.C. § 259(b)

Summary of FPASA. The preamble to the Proposed Rule also cites two sections of the FPASA, apparently as support for part or all of the rule and the proposed supplemental GSAR clause. The first cited provision, Section 201(a) of FPASA, authorizes the GSA to "procure and supply personal property and nonpersonal services for executive agencies to use in the proper discharge of their responsibilities."[28] The

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[25] *See* TRICARE, Federal Pricing Forum Questions (answering questions raised at the May 11, 2004 Industry Conference re: TRRx), *available at* http://www.tricare.osd.mil/pharm_mfg/downloads/FederalPricingForumQuesAns_Final.pdf (posted Oct. 28, 2004) ("GSA does not have jurisdiction over TRICARE or the application of Federal ceiling prices to TRRx under [the VHCA]").

[26] Price Reductions (May 2004), 48 C.F.R. 552.238-75.

[27] 70 Fed. Reg. at 19,050.

[28] 40 U.S.C. § 501(b)(1)(A).

second cited provision, Section 309, is a FPASA definitional section that includes procedures established by the GSA for the award of multiple award schedule contracts (such as FSS contracts) within the definition of "competitive procedures" if: (1) participation in the multiple award program is "open to all responsible sources"; and (2) contracts awarded through the GSA procedures result in "the lowest cost alternative to meet the needs of the government."[29] Thus, Section 309 provides that "competitive procedures" are those procedures under which an "executive agency" enters into a contract pursuant to full and open competition, and that the term "competitive procedures" can include those procedures adopted by the GSA relating to the award of multiple award schedule contracts.

Congressional Purpose of FPASA. The purpose of FPASA is to empower the GSA "to provide the Federal Government with an economical and efficient system for . . . procuring and supplying property and nonpersonal services."[30] Congress authorized the GSA "to regulate the policies and methods of executive agencies with respect to the procurement and supply of personal property and nonpersonal services."[31] For purposes of FPASA, the term "procurement" means "all stages of the process of acquiring property or services, beginning with the process for determining a need for property or services and ending with contract completion and closeout."[32]

FPASA Does Not Authorize the Proposed Rule. Neither of the two FPASA provisions cited by the GSA (nor any other FPASA provision) authorizes the Proposed Rule. As noted, FPASA permits the GSA to establish procedures that govern the procurement of property and services for use by executive agencies. For the reasons described in the discussion of the VHCA above, the retail pharmacy program authorized by the Proposed Rule does not involve Federal procurement of the covered drugs that would pass through the retail pharmacy program. Accordingly, the cited FPASA provisions do not apply.

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[29] 41 U.S.C. § 259(b).

[30] 40 U.S.C. § 101.

[31] H.R. Rep. No. 670, 81st Cong., 1st Sess. (1949), *reprinted in* 1949 U.S. Code Cong. & Admin. News 1475.

[32] 41 U.S.C. § 403.

Moreover, FPASA does not contemplate the establishment of procedures, such as those in the Proposed Rule, under which a Federal agency's instruction to a retail pharmacy to use its commercial inventory to fill a prescription for an agency beneficiary could be deemed an order under an FSS contract of the drugs used to fill the prescription. As described in section B below, an order must be placed "directly with the contractor in accordance with the terms and conditions of the pricelists."[33] Deemed orders do not meet this requirement. In short, there is no nexus between FPASA and the Proposed Rule's provision that an instruction from a Federal agency to a retail pharmacy can substitute for an authorized entity's order under an FSS contract.[34]

The GSA's Prior Interpretations of FPASA Do Not Permit Agency Instructions to be "Deemed" Orders under FSS Contracts. The GSA has issued an order (the "GSA Order") that identifies the entities and organizations that are eligible to order supplies and services from FSS contracts.[35] The GSA Order confirms that FSS contracts can be used to "procure and supply personal property and non-personal services for executive agencies and other Federal agencies, mixed-ownership Government corporations as identified in the Government Corporation Control Act, the District of Columbia, and qualified nonprofit agencies for the blind or other severely handicapped for use in making or providing an approved commodity or service to the Government."[36] The GSA Order also explains that other organizations may be eligible to order from the FSS pursuant to other sections of FPASA or "by reason of enabling statutory authority."[37]

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[33] FAR § 8.406-1.

[34] *See Liberty Mut. Ins. Co. v. Friedman*, 639 F.2d 164 (4th Cir. 1981) (citing *Chrysler Corp. v. Brown*, 441 U.S. 281, 308 (1979)) (To establish that a regulation is promulgated pursuant to power conferred by Congress, there must be a "nexus between the regulation[] and some delegation of the requisite legislative authority by Congress.").

[35] GSA Order ADM 4800.2E (Jan. 3, 2000) ("GSA Order").

[36] GSA Order at ¶ 3.

[37] GSA Order at ¶ 3; *accord, id.* at ¶ 7 ("Organizations are eligible to use GSA sources of supply and services pursuant to the Property Act or other statutory authority"). The Scope of Contract clause in the FSS contracts recognizes a further potential limitation: an FSS contractor is not obligated to accept orders that are not "received from activities within the Executive Branch of the Federal Government." *See* I-FSS-103 Scope of Contract – Worldwide (July 2002). Thus, although approved cost reimbursement contractors can order from the FSS, the FSS contractor is not required to accept orders from those cost reimbursement contractors.

The GSA Order confirms that authority under a statute or a properly issued regulation – *i.e.*, a regulation that is within the scope of existing statutes and that does not conflict with acquisition regulations – is required before a new entity can be granted access to the FSS. As discussed above, the drugs dispensed through a Federal Agency Retail Pharmacy Program would be purchased by an agency beneficiary and filled from the retail pharmacy's commercial inventory. The drugs would not be ordered by an executive agency under an FSS contract. The Proposed Rule is thus not consistent with the GSA Order. Moreover, the expansive concept of a "deemed" order (in lieu of an actual order) that underlies the Proposed Rule could set a dangerous precedent that could apply to FSS contracts for other products, and thereby result in a slippery slope that could undermine the integrity and upset the economics of the GSA FSS contracting system. For these reasons, implementation of the Proposed Rule would violate FPASA and would exceed the GSA's authority.

3. National Defense Authorization Acts of 1999 and 2000, 10 U.S.C. § 1074g

Citing the National Defense Authorization Acts of 1999 and 2000, the preamble to the Proposed Rule also suggests that the Proposed Rule is "required by DoD in order to reengineer its TRICARE Pharmacy Benefits Program."[38] The cited authorization statutes directed the DoD to "establish an effective, efficient, integrated pharmacy benefits program" and to incorporate "the best business practices of the private sector" in implementing the program redesign.[39]

No provision in either of these authorization statutes would allow the GSA to extend the scope of FSS contracts in the unprecedented manner proposed in the rule. Rather, these statutes required the DoD to develop a uniform formulary through which its beneficiaries would be able to receive a uniform and integrated health benefit throughout the three points of service in the TRICARE health system: Military Treatment Facilities ("MTFs"), the TRICARE Mail Order Pharmacy ("TMOP"), and retail pharmacies. The DoD promulgated regulations implementing these statutory requirements in April 2004.[40]

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[38] 70 Fed. Reg. at 19,046.

[39] 10 U.S.C. § 1074g(a). This statute applies only to the DoD. It would not have any bearing on a retail pharmacy benefit offered by the VA, the PHS or the Coast Guard.

[40] 69 Fed. Reg. 17,035 (Apr. 1, 2004).

Under those regulations, TRICARE beneficiaries who purchase their drugs in network retail pharmacies are required to pay $3 for a 30-day supply of generic drugs; $9 for a 30-day supply of drugs that the DoD Pharmacy and Therapeutics ("P&T") Committee determines to meet its standards of clinical and cost effectiveness; and $22 for a 30-day supply of drugs that the P&T Committee determines not to meet its standards of clinical and cost effectiveness. For those same cost shares, a TRICARE beneficiary can obtain a 90-day supply of the same prescription drugs through the TMOP. TRICARE beneficiaries do not pay a cost share for drugs obtained in MTFs.

The Proposed Rule would not affect these beneficiary cost share requirements or increase beneficiary access to prescription drugs. It would, however, reduce the DoD's costs for covered drugs that are dispensed in network retail pharmacies. Thus, finalization of the Proposed Rule could incentivize the DoD to promote utilization of the retail pharmacy point of service, where the DoD has set higher beneficiary cost-sharing amounts. Contrary to helping beneficiaries to obtain affordable medicines, the Proposed Rule could have the opposite effect.

We also do not believe that expansion of FSS contract pricing in the manner suggested in the Proposed Rule would be consistent with the "best business practices of the private sector." Rather, expansion of the FSS contracts to commercial sales in the manner suggested in the Proposed Rule would directly conflict with private sector practices. Federal pricing, including the Price Reductions clause in the FSS contracts and the price ceiling mandated by the VHCA, does not apply in the private sector and is not a commercial business practice.

The business practices of the private sector do include a number of models that are available to the DoD (and other Federal agencies) that could be used to help contain drug acquisition costs. For example, it is commonplace in the private sector for purchasers or their agents to negotiate rebate agreements with manufacturers and use a variety of tools to achieve cost savings.[41] Such a system could work well within the DoD and would be consistent with what Congress intended when it directed the DoD to

[41] The DoD's PBM apparently is prohibited by contract from negotiating or collecting rebates of any type from pharmaceutical manufacturers. Contract MDA 906-03-C-0019 at 5 (Sept. 26, 2003). This contract provision may be inconsistent with the statutory requirement that the DoD incorporate "the best business practices of the private sector" into its TRICARE healthcare system.

incorporate the best business practices of the private sector into its TRICARE health system.[42]

B. The Proposed Rule Is Inconsistent with the FAR

The "deemed order" requirement of the proposed "Federal Agency Retail Pharmacy Program" GSAR clause also would be invalid because it directly conflicts with the Federal Acquisition Regulations ("FAR"). Among other clauses, FAR 9.403 ("Definitions") expressly lists reimbursement transactions, such as insurance and government subsidies, within the definition of "nonprocurement transactions." By contrast, the Proposed Rule concludes that Federal agency reimbursement of a prescription drug claim made by one of the agency's beneficiaries constitutes a "procurement" transaction under the FSS contract and/or a depot contract. The Proposed Rule's conclusions in these regards are in direct conflict with the FAR.

Similarly, FAR 8.406-1 ("Order Placement") provides that an "ordering activity shall place an order directly with the contractor in accordance with the terms and conditions of the pricelists" and then proceeds to specify the terms that must be included in the order. Under the Proposed Rule, however, no order would be placed "directly" with the FSS contractor. Instead, orders would be "deemed" to occur when a Federal agency instructs the retail pharmacy to fill a prescription order requested by one of the Federal agency beneficiaries, a transaction to which the FSS contractor is not a party and over which it has no control.

The proposed clause tries to avoid this conflict with the FAR's ordering provisions, at least in part, by declaring in subsection (a) that certain FAR clauses that are not consistent with the proposed clause would not apply to Federal Agency Retail Pharmacy Programs.[43] However, this approach would be insufficient. The FAR precludes agencies from promulgating supplemental acquisition regulations, such as the proposed clause, unless they are: (a) necessary to implement FAR policies and procedures within the agency; or (b) additional policies, procedures, solicitation

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[42] *See* Gen. Accounting Off., Pub. No. GAO/HEHS-98-176, Defense Health Care: Fully Integrated Pharmacy System Would Improve Service and Cost-Effectiveness 37 (June 1998) ("TRICARE contractors . . . are less able to negotiate deeper price discounts from drug companies without the ability to provide preferred or favorable status on a closed or incentive-based drug formulary").

[43] 70 Fed. Reg. at 19,050.

provisions, or contract clauses that supplement the FAR to satisfy the needs of the agency.[44] Here, the proposed clause conflicts with the FAR, and would not further the needs of the GSA (the agency promulgating the regulation). Rather, by its terms, the clause would affect only the VA, the DoD, the PHS, and the Coast Guard – not the GSA. Because it does not comport with FAR requirements for supplemental agency clauses, the proposed clause would be an invalid exercise of the GSA's authority.[45]

C. The Proposed Rule Improperly Augments Appropriations

A Federal agency may not augment its appropriations by accepting money or gifts from outside sources without specific Congressional authorization.[46] A corollary to this rule is that Federal agencies are not allowed to impose fees or accept voluntary services in the absence of statutory authority.[47] In conflict with the anti-augmentation statutes, the Proposed Rule would permit the DoD (and other Federal agencies) to increase appropriations in the form of rebates collected from manufacturers.[48] Because there is no statutory authority for the agencies to increase their appropriations in this fashion, implementation of the Proposed Rule would result in a violation of appropriations law.[49]

Related to the augmentation issue, the GSA claims that, because the Senate Report that accompanied the FY 2005 DoD Authorization Act decreased funding for the defense health program account and estimated savings from the TRRx Program, "Congress has anticipated the extension of Federal pricing to the redesigned TPBP [TRICARE Pharmacy Benefit Program]." The Senate Report reflects an expectation of savings, not an endorsement of the TRRx Program. The FY 2005 DoD Authorization

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[44] FAR § 1.302 (2005).

[45] *See Service Employees Int'l Union v. Gen'l Servs. Admin.*, 830 F. Supp. 5, 9-10 (D.D.C. 1993) (GSA supplemental regulation held improper because it was contrary to a FAR clause and did not address a specific GSA need).

[46] *See* 31 U.S.C. § 3302(b) (1982); 31 U.S.C. § 1301(a) (1992).

[47] 31 U.S.C. § 1342 (1996).

[48] 70 Fed. Reg. at 19,046, 19,050.

[49] *See Scheduled Airlines Traffic Offices, Inc. v. Dept. of Defense*, 87 F.3d 1356 (D.C. Cir. 1996) (fee collected by government from travel agents under concession contracts and without Congressional authorization was an improper augmentation of appropriations and monies had to be returned to the Treasury).

Act does not contain any language supporting or authorizing the expansion FSS pricing to a retail pharmacy program. Rather, the citation is to a statement in a Senate Report, which was not enacted into law.[50]

II. If Not Withdrawn, the Proposed Rule Should Be Clarified

In addition to our serious concerns about the GSA's legal authority to implement the Proposed Rule, the Proposed Rule is ambiguous in several respects and would cause significant operational difficulties if implemented. In the event that the rule is not withdrawn, as it should be, PhRMA respectfully requests that the GSA clarify and/or reconsider the following additional elements of the Proposed Rule.

1. ***Contract Modification.*** The Proposed Rule contemplates that a supplemental clause, known as the "Federal Agency Retail Pharmacy Program Supply Schedule," would be added to the GSAR and then could be incorporated into FSS contracts. The Proposed Rule is silent concerning the method that the GSA and/or the VA would use to incorporate the new clause into FSS contracts. In this regard, PhRMA emphasizes Clause 52.212-4, Contract Terms and Conditions – Commercial Items (FEB 2002) (TAILORED), a standard clause in the FSS contracts, which provides that "[c]hanges in the terms and conditions of this contract may be made only by written agreement of the parties." Accordingly, a unilateral modification of existing FSS contracts to add this clause would constitute a breach of contract. PhRMA requests clarification from the GSA that current FSS contracts will not be unilaterally modified to add the new clause. Further, PhRMA requests that the GSA explain precisely how it and/or the VA plan to implement this clause if the Proposed Rule were to become final.

2. ***Scope of Coverage***. By its terms, the proposed clause would apply only to "covered drugs" dispensed through qualifying retail pharmacy programs. PhRMA understands that the GSA intends for the rebate obligations prescribed in the clause to apply only to "covered drugs" as that term is defined in the VHCA. If our understanding in this regard were correct, then the scope of coverage of the new clause would be more limited than the scope of coverage of the Schedule 65 FSS contract into which the clause

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[50] Although legislative history may be useful "in resolving ambiguities and determining congressional intent, it is the language of the appropriation act, and not the language of its legislative history, that is enacted into law." GAO Principles of Federal Appropriations Law, Vol. 1, at 2-45 (3d ed. Jan. 2004) (citing *Shannon v. U.S.*, 512 U.S. 573, 583 (1994)).

would be incorporated. The VHCA defines "covered drugs" to include innovator drugs (both single and multiple source) and biological and insulin pharmaceutical products.[51] The Schedule 65 FSS contract covers not only "covered drugs," but also non-innovator multiple source pharmaceuticals. PhRMA requests that the GSA confirm whether this distinction was intentional and, if so, to explain the rationale for limiting the scope of the proposed clause in this fashion.

3. ***Scope of the "Deemed Order" Concept.*** Both the preamble to the Proposed Rule and subsection (b) of the proposed GSAR clause note that covered drugs dispensed through a qualifying retail pharmacy program "will be deemed to have been ordered by the Federal agency through the FSS contract, for the purposes of establishing price, delivery, and scope of coverage," but that the Proposed Rule "does not confer rights for any other purpose."[52] The GSA specifically should identify the "other purpose[s]" that are being referenced. The GSA also should explain how an agency instruction to a retail pharmacy to fill a prescription from the pharmacy's commercial stock can be deemed an order under the FSS contracts for certain purposes, such as to establish pricing, but not for other matters involved with the traditional ordering process.

4. ***Issues Concerning the Calculation of the Rebate Amount.*** Under the proposed clause, rebates would be calculated quarterly based on the difference between a benchmark price (either the actual sales price charged to the wholesaler or retail pharmacy chain if known and auditable or the non-FAMP) and the lower of the FSS price or FCP for the drug in question.[53] PhRMA has a number of concerns about the proposed method for calculating the amount owed.

A. ***Party To Determine the Benchmark Price.*** The Proposed Rule does not specify the party that would determine the benchmark price that should be used. The GSA should clarify whether the Federal agency or the contract holder would determine whether to use the non-FAMP or the actual sales price in calculating the rebate amount. It should be the contract holder's decision regarding which benchmark to use, because the

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[51] 38 U.S.C. § 8126(h)(2).

[52] 70 Fed. Reg. at 19,046, 19,050.

[53] 70 Fed. Reg. at 19,050.

contract holder is in the best position to know the prices that it receives for its products from wholesalers and/or retail pharmacy chains.[54]

B. ***The Rebate Formula Will Not Result in the FSS Price or the FCP.*** The rebate formula apparently is intended to enable the Federal agency administering the retail pharmacy program to obtain the FSS price or the FCP for covered drugs sold through the retail pharmacy program. However, applying the formula described in the Proposed Rule will not achieve either of these intended effects.

Taking the DoD's TRRx Program as an example, the proposed calculation would not take into account the price that the DoD actually pays for drugs dispensed in retail pharmacies or that beneficiary cost shares in the TRICARE system are higher in the retail pharmacy sector than in the TMOP or MTFs. For this reason, it is possible that, under the formula in the Proposed Rule, the DoD (though not the beneficiary) could end up paying less for drugs dispensed in retail pharmacies than in the other points of service. Moreover, the formula in the Proposed Rule would not result in the government obtaining the FSS price or the FCP. Instead, the most that the rebate formula will obtain is an approximation of the FSS price or the FCP (that is, the difference between the non-FAMP for a drug and the drug's FSS price or the FCP). We request clarification as to how the VHCA (or some other statute) authorizes a rebate methodology that would not result in the government obtaining either the FSS price or the FCP.

C. ***The Rebate Formula Does Not Differentiate between Embedded and Absorbed IFF Payments.*** Some FSS contractors incorporate the IFF payment into their FSS prices, thereby resulting in an FSS price that is increased by .5%. The purpose of this approach is to enable the ordering agency to pay the IFF to the contractor. The contractor then remits the IFF to the VA on a quarterly basis as required. Other contractors absorb the IFF payment, meaning that FSS prices are not adjusted to include payment of the IFF by the ordering agency. The formula in the Proposed Rule does not distinguish between those contractors who embed the IFF in their FSS prices and those contractors who absorb the IFF payment. To ensure that the intent of the parties where the contractor embeds the IFF payment is maintained, the Proposed Rule should clarify

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[54] *See, e.g.,* TRICARE, Process and Procedures Guide for Manufacturer Refunds, Version 2.1, 11. *available at* http://www.tricare.osd.mil/pharm_mfg/downloads/Policies_and_Procedures_Guide_2-1.pdf (last updated Mar. 24, 2005) (indicating that choice of benchmark price would be "at the discretion of the manufacturer").

that the benchmark price for the rebate for contractors who embed the IFF is the negotiated FSS price for each drug plus .5% (the "IFF" amount).

D. ***The Rebate Formula Could Lead to Unreasonable Results.*** Under the VHCA, it is possible for the FCP for certain drugs to be artificially set at $.01. This result, known as "penny pricing," occurs when the price of a covered drug substantially increases from one year to the next such that the additional discount mandated by the VHCA causes the FCP for the covered drug to be a negative number. In such circumstances, VA by policy sets the FCP for the covered drug at $.01.[55] For those drugs that are penny priced, the formula in the Proposed Rule could lead to absurd results. The benchmark price (either the actual sales price or the non-FAMP) would far exceed the FCP (which would be $.01). Accordingly, the amount owed for such drugs could be considerably higher than the government's acquisition costs, particularly if the beneficiary cost share for the drugs is higher, such as for a Tier 3 drug (the tier with the $22 cost share) on the DoD's uniform formulary. Such a result could not possibly be intended by law and is further reason why the rule is irrational and unauthorized.

5. ***Issues Concerning the Schedule for Submission of Rebates, Payment of the IFF, and the Disputes Process.*** The Proposed Rule contemplates that a Federal agency administering a retail pharmacy program would provide utilization flat file layout reports to FSS contract holders on the 15th day of the first month after the close of a calendar quarter.[56] The manufacturer would then have 70 days to calculate the rebate amount owed, reconcile the calculation with the Federal agency calculation, and pay the rebate.[57] Thus, the rebate amount would be due 85 days after the close of each calendar quarter. Additionally, we understand that the proposed clause would require FSS contract holders to report retail pharmacy sales and pay the IFF on those sales in accordance with the VA's variation of clause 552.238-74, Industrial Funding Fee and Sales Reporting (JUL 2003) (VARIATION), which requires FSS contract holders to report their quarterly sales and make the IFF payment within 60 days of the close of the reporting period. As we understand the proposed GSAR clause, the 60-day reporting requirement would be triggered for retail pharmacy sales at the end of the quarter in which the rebate

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[55] *See, e.g.*, Letter from William E. Thomas, Jr.. Assistant General Counsel, Dep't. of Veterans Affairs, to Manufacturer (Dec. 30, 1992). (Attached as Exhibit E).

[56] 70 Fed. Reg. at 19,050.

[57] 70 Fed. Reg. at 19,051.

calculation is made, not at the end of the quarter in which the retail pharmacy transaction occurs. For example, as we read the clause, retail pharmacy sales that occur in the fourth calendar quarter of a year need not be reported until 60 days after the close of the first calendar quarter of the following year. PhRMA requests clarification that its understanding in this regard is correct.

A related issue arises if a contract holder and the Federal agency disagree about the amount that is due for a particular quarter. Under those circumstances, the proposed clause as written would require the contract holder to pay the rebate according to the agency's calculation (including the disputed amount) and then use "best good faith efforts" to resolve the dispute within 60 days.[58] Only after the completion of the 60-day negotiation period would the contract holder be permitted to file a claim pursuant to the Disputes clause. PhRMA has three concerns with this provision.

A. ***Payment of Rebates During Pendency of a Dispute.*** In the event of a disagreement, the proposed clause would require FSS contract holders to pay the entire rebate amount, including the portion in dispute, pending resolution of the dispute.[59] This approach is different from the approach taken in connection with the Medicaid Rebate statute. In the event of a dispute concerning the amount of the rebate that is due under the Medicaid Rebate statute, the Rebate Agreement requires manufacturers to pay only "that portion of the rebate amount claimed which is not disputed" and to pay any balance plus interest by the "due date of the next quarterly payment . . . after resolution of the dispute."[60] A similar approach should be adopted here.

B. ***IFF Refunds if Contractor Prevails in a Dispute.*** The retail pharmacy clause as currently written is silent on whether the VA would be required to remit the affected portion of the IFF (with interest), either by refund or offset, in the event that good faith negotiations or a court decision subsequently result in a reimbursement of part of the refund to the contractor. If the Medicaid Rebate approach were adopted, contract holders could make disputed refund payments and IFF payments during the quarter immediately following the resolution of the dispute. If the GSA chooses not to adopt the Medicaid

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[58] 70 Fed. Reg. at 19,051.

[59] 70 Fed. Reg. at 19,051.

[60] Sample Medicaid Drug Rebate Agreement § V(b), *available at* http://www.cms.hhs.gov/medicaid/drugs/rebate.pdf.

Rebate approach, at a minimum the retail pharmacy clause should be modified to require the VA to remit the portion of the IFF that is attributable to disputed refund amounts on which the FSS contract holder's position ultimately prevails, plus interest.

C. ***The Proposed Clause Would Be Inconsistent with the Contract Disputes Act.*** The 60-day mandatory negotiation period would be inconsistent with the Contract Disputes Act ("CDA"), 41 U.S.C. § 601, *et seq.* In particular, section 605(d) of the CDA provides in pertinent part:

> Notwithstanding any other provision of this chapter, a contractor and a contracting officer may use any alternative means of dispute resolution under subchapter IV of chapter 5 of Title 5, or other mutually agreeable procedures, for resolving claims. The contractor shall certify the claim when required to do so as provided under subsection (c)(1) of this section or as otherwise required by law.

While this provision authorizes voluntary use of alternative dispute resolution procedures, it does not permit mandatory periods of negotiation or other administrative exhaustion requirements beyond those required by the CDA. For this reason, the GSA should delete subsections (h)(2) and (h)(3) of the proposed GSAR clause and replace them with a requirement that FSS contract holders process all disputes concerning the proper amount of the rebate owed under the retail pharmacy clause through the Disputes clause in the FSS contracts. PhRMA agrees, however, that resolution of such disagreements through good faith negotiations would be preferable to a formal dispute. The GSA could make such an option available to the parties by adding a provision that would authorize voluntary negotiation of disagreements over the amount of a rebate, but which would make clear that contractors would not have to exhaust that voluntary negotiation process before initiating the disputes process.

6. ***Clerical Revisions***. The proposed clause contains two references to the DoD that PhRMA believes may be clerical mistakes. First, in subsection (g)(1)(iv), the clause refers to the Department of Defense's Accrual Fund and the Defense Health Program account as the source of funding for a retail pharmacy program.[61] These accounts would be available only for the TRRx Program and would not apply to retail pharmacy

[61] 70 Fed. Reg. at 19,050.

programs administered by the VA, the PHS or the Coast Guard. Second, subsection (g)(3) would require that rebate payments be "received by DoD" not later than 70 days following the date of the utilization file for the quarter.[62] Again, we assume that the DoD would be the recipient of rebates only for the TRRx Program and not for any other qualifying retail pharmacy programs.

7. ***References in the Clause to Terms and Conditions of Commercial Agreements.*** The proposed clause refers in subsection (d) to the terms and conditions of commercial agreements between the FSS contract holder and the retail pharmacies or wholesalers.[63] Specifically, that subsection would provide that the time and methods of payments to the FSS contract holder for FSS items deemed to have been ordered through the retail pharmacy program would be determined in accordance with the terms and conditions of commercial agreements between the manufacturers and the retail pharmacies or their wholesalers. The terms of a commercial agreement cannot control parties' obligations under an FSS contract. The GSA's reliance on the terms of the contracts between manufacturers and retail pharmacies or wholesalers further demonstrates that there is no contract under which Federal agencies procure the covered drugs that would be dispensed through a retail pharmacy program. In the absence of such a contract, the Proposed Rule is improper.

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[62] 70 Fed. Reg. at 19,051.

[63] 70 Fed. Reg. at 19,050.

III. Conclusion

PhRMA appreciates the opportunity to submit these comments on the Proposed Rule. As explained above, the Proposed Rule raises a number of important policy, legal, and implementation issues. PhRMA remains committed to working with DoD, VA, and others in the Federal government to develop alternatives to the Proposed Rule that can accommodate the concerns raised by all parties in a manner that is consistent with existing laws.

We appreciate your consideration of our comments.

Sincerely,

Richard I. Smith
Senior Vice President Policy,
Research, and Strategic Planning

Diane E. Bieri
Vice President and
Acting General Counsel

cc: (by hand delivery)

The Honorable David Safavian
Director, Office of Federal Procurement Policy

PhRMA's Comments on GSAR Case No. 2005-G501

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DEPARTMENT OF VETERANS AFFAIRS
Office of the General Counsel
Washington DC 20420

NOV 01 2001

In Reply Refer To:

Robert D. Seaman, Esq.
General Counsel
TRICARE Management Activity
Skyline Five, Suite 810
5111 Leesburg Pike
Falls Church, Virginia 22041-3106

Dear Mr. Seaman:

I have reviewed your letter of September 17, 2001, asking that the Department of Veterans Affairs (VA) concur in your opinion that purchases of covered drugs under the retail portion of a proposed new TRICARE Pharmacy Benefit Program (TPBP) qualify for Federal ceiling prices (FCP) under the Veterans Health Care Act of 1992 (VHCA), Section 603, 38 U.S.C. 8126. I recently shared your letter with VA's Public Law 102-585 (P.L.) Policy Group at their annual meeting, and they reviewed the arguments presented in support of your position as well as the diagram attached to your letter.

After some discussion, the Policy Group requested that I obtain further input from your agency concerning the nature of your request and your understanding of how the TPBP will function. Preliminarily, the Policy Group wishes to know whether your agency is requesting approval for full Federal Supply Schedule (FSS) pricing for all retail prescription purchases under the TPBP or whether your position is simply that such purchases are entitled to FCPs under the VHCA.

Also, the Policy Group would appreciate receiving your comments on what has been the standard VA interpretation of the statutory definition of "depot", contained in 38 U.S.C. 8126(h)(3). VA has consistently interpreted the two prongs of that definition as being limited to centralized commodity management systems through which covered drugs are: (A) received, stored and delivered to a listed Federal agency through a federally-owned warehouse system or a commercial warehouse system operating under contract with the procuring Federal agency, or (B) delivered directly from the manufacturer or its agent to a listed Federal agency's ordering activity at its purchasing address. Prior to receiving your letter, we have never viewed a Federal agency's pharmacy benefits office (PBO) and its contracted commercial pharmacy benefits manager (PBM) as a "centralized commodity management system" within the definition of "depot". We also have not previously viewed the term "entity" as being as unlimited and broadly defined as you state in your letter.

Robert D. Seaman, Esq.

Because your agency shared details of the new TPBP with some representatives of the pharmaceutical industry, private law firm attorneys in Washington, DC have begun to discuss the program and react to it. Recently, one such attorney described the program as being merely "an insurance reimbursement scheme". The P.L. Policy Group would appreciate receiving your reaction to that characterization, along with a summary by TMA of all industry reactions noted during any meetings with representatives of covered drug manufacturers. Also, a practical question has been raised as to how DoD's PBO would deal with package size differences between FSS NDC units and retail pharmacy dispensing units, when the PBO applies for FSS or FCP "rebates".

Finally, the Policy Group is puzzled by your diagram's treatment of prescriptions filled by "non-network retail pharmacies". It is the Policy Group's opinion that such pharmacies have no contractual relationship whatsoever with DoD's PBO and/or its contracted PBM and, thus, will be dispensing pharmaceuticals that are not covered by the VHCA.

I understand that TMA is interested in obtaining an opinion from VA on the matters specified in your letter as quickly as possible. However, as you know from the history our two agencies' interactions concerning TRICARE Pharmacy Benefits, the TPBP presents serious and difficult questions of application of the VHCA, and the Policy Group wishes to be fully informed prior to making any recommendations. Once I receive your response to this letter, I will convene the Policy Group and attempt to obtain a prompt decision from them on the position that you set forth. Thank you for your cooperation in this matter.

Sincerely yours,

Phillipa L. Anderson
Assistant General Counsel

cc: Deputy Assistant General Counsel (025C)
Associate Chief Consultant, PBM (119D)
Director FSS Contracting (90N-M1)
Audit Team Leader (52C)
PBM Data Base Manager (119D)
Senior Contract Attorney (025NAC)

DEPARTMENT OF VETERANS AFFAIRS
Office of General Counsel
PO Box 76
Hines IL 60141

July 28, 1994

In Reply Refer To: 025

Lt. Col. Henry L. Smith
OASD (HA) HSF/MCO
The Pentagon, Room 1B657
Washington, DC 20301-1200

RE: Applicability of Public Law 102-585 to USTF's and DoD Health Care Contractors' Drug Procurements

Dear Lt. Col. Smith:

Pursuant to our telephone conversation on July 26, 1994, I am writing to request the position of the Department of Defense (DoD) on the applicability of Section 603 of the Veterans Health Care Act of 1992 (P.L. 102-585; 38 U.S.C. 8126 (a) et seq.) to covered drug procurements made by Uniformed Services Treatment Facilities (USTFs), the Civilian Health and Medical Program of the Uniform Services (CHAMPUS) and its mail order prescription contractor, Diagnostek, Inc./Health Care Services, Inc. (HCS).

As you know, P.L. 102-585 requires all manufacturers of covered drugs who wish to receive payment for their drugs sold to Medicaid Plans, the Department of Veterans Affairs (VA), the Public Health Service (PHS), DoD or any entity that receives funds under the Public Health Service Act, to enter into an agreement with VA to grant a minimum 24 percent discount on covered drugs to DoD, VA and PHS. The Law also requires them to make available all of their covered drugs on the Federal Supply Schedule (FSS) administered by VA. The Statute does not require manufacturers to grant the discount to any government agencies other than VA, DoD and PHS (including the Indian Health Service) or to grant it to government contractors authorized to use the FSS. (38 U.S.C. 8126(a)(2) and (b).)

To accommodate the limited nature of this congressionally imposed covered-drug discount, VA has allowed manufacturers to choose whether they will, for ease of administration, provide the discount to all users of the FSS or whether they will print two price lists--one containing Federal ceiling prices for VA, DoD and PHS, and the other containing the standard FSS prices negotiated according to GSA guidelines. Approximately 35 manufacturers have elected to print two price lists under the FSS and, thus, to limit the beneficiaries of the discount required by the Statute.

July 28, 1994

Lt. Col. Henry L. Smith
OASD (HA) HSF/MCO

VA has the responsibility to administer and enforce Section 603 of P.L. 102-585, and, in that role, has received inquiries and complaints from covered drug manufacturers regarding recent bulletins and instructions issued by DoD's Defense Personnel Support Center (DPSC). On May 29, 1994, Contracting Officer Roger Dixon of DPSC wrote a memo to "All DPSC DAPA Holders and Prime Vendors" informing them that "...USTF facilities are eligible to receive the same Government pricing structure offered to all other DoD facilities using the DPSC Prime Vendor program." Also, on July 25, 1994, Contracting Officer Paul Vasquez wrote to drug manufacturers announcing the award of a mail order pharmacy contract to Diagnostek, Inc./Health Care Services, Inc. (HCS) and informing them that the contract authorizes the vendor to utilize Government sources of supply, as directed by Congress. The letter stated that "HCS may be contacting you for the procurement of pharmaceuticals..." and that "[t]he procuring of these pharmaceuticals is solely the responsibility of HCS." With regard to payment, "DPSC shall not be included in any of these arrangements."

Syntex Laboratories, Inc., a dual pricing covered drug manufacturer, has asked VA whether it is statutorily required under DPSC's instructions to sell its covered drugs to CHAMPUS and USTFs at Federal ceiling prices contained in its price list for VA, DoD and PHS. At present, we lack sufficient information to answer this question. Consequently, VA would like to receive information and input in writing from DoD on two questions:

1) Does DoD intend that USTFs and CHAMPUS contractors, as well as mail order pharmacies with DoD contracts, purchase covered drugs in the name of DoD at statutory Federal ceiling prices (when these are the lowest prices available) or does DoD intend to have these organizations purchase drugs at the regular FSS negotiated contract price?

2) If the above organizations are to procure covered drugs at Federal ceiling prices, how does DoD propose to set up these transactions and interpret the Statute so as to extend the discount to USTFs and CHAMPUS? (Please also send copies of standard DoD agreements with these organizations.)

July 28, 1994

Lt. Col. Henry L. Smith
OASD (HA) HSF/MCO

I would appreciate it if you would communicate these questions to the DoD attorneys responsible for dealing with these matters so that VA can respond to Syntex's and other manufacturers' inquiries as soon as possible. Melbourne A. Noel, Jr. of this office would be happy to discuss interpretation and application of the Statute with any DoD personnel. He may be reached at (708) 216-2504. Please be assured that VA's goal is for the Government to derive from P.L. 102-585 the maximum financial benefit that can be justified by its language and the intent of Congress in drafting it.

Sincerely yours,

Mel Noel, Jr.

for William E. Thomas, Jr.
Assistant General Counsel

cc: Office of General Counsel (025NAC)
Associate DAS for the NAC (90N)
Director, Acquisition Analysis & Liaison Staff (96)
Chief, Clinical Pharmacy (111H)
Chief, D&PPM/VACO (119D)

Response Number	Date Received	Comment Date	Commenter
2005-G501-7	06/13/05	06/13/05	PRMA
2005-G501-8	06/13/05	06/13/05	Merck & Co., Inc
2005-G501-9	06/15/05	06/09/05	Coalition for Government Procurement

Attachments

2005-G501-1

DONNA LEE YESNER
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EMAIL ADDRESS
dyesner@mckennalong.com

June 7, 2005

BY FACSIMILE AND HAND DELIVERY

General Services Administration, Regulatory Secretariat (VIR)
1800 F Street, NW
Room 4035
Washington, DC 20405

ATTN: Laurieann Duarte

Re: Comments on GSA Acquisition Regulation, Federal Agency Retail Pharmacy Program - GSAR Case 2005-G501

Dear Ms. Duarte:

The sanofi-aventis Group, commenting for both Sanofi-Synthelabo Inc. and Aventis Pharmaceuticals, appreciates this opportunity to comment on the proposed rule published by the General Services Administration ("GSA") in the Federal Register on April 12, 2005 concerning Federal Agency Retail Pharmacy Program transactions ("Proposed Rule"). sanofi-aventis is committed to the fight against disease worldwide. In the new millennium, we have taken up the major challenges of discovering new compounds that are essential to the progress of medical science and launching pharmaceutical products all over the world that constitute real therapeutic progress for patients. Our mission is to discover, develop, and make available to physicians and their patients innovative, effective, well-tolerated, high quality treatments that fulfill vital health care needs. Backed by a world-class research and development organization, we are developing leading positions in seven major therapeutic areas: cardiovascular disease, thrombosis, oncology, diabetes, central nervous system, internal medicine, and vaccines.

The Proposed Rule would create a new clause entitled "Federal Agency Retail Pharmacy Program Supply Schedule" to be inserted in the Federal Supply Schedule ("FSS") contracts between the Veterans Administration ("VA") (under a delegation of authority from GSA) and manufacturers of certain products, *i.e.*, drugs, pharmaceuticals, and hematology-related products listed on Schedule 65, Part I, Section B of the FSS (the "Proposed Rule"). The FSS contract allows authorized buyers to purchase these products at most favored customer prices. Pursuant to Section 603 of the Veterans Health Care Act of 1992 ("VHCA"), 38 U.S.C. § 8126, the price charged the VA, Department of Defense ("DoD"), the Public Health Service ("PHS") and the Coast Guard (the "big four agencies") under the contract for a drug covered by the VHCA cannot

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exceed a Federal Ceiling Price ("FCP") irrespective of the most favored customer price for the drug. Under the proposed clause, the big four agencies would be authorized to use the FSS contract prices for covered drugs to obtain rebates on purchases by beneficiaries from retail pharmacies participating in a "Federal Agency Retail Pharmacy Program," if the program is modeled after the DoD's TRICARE Retail Pharmacy ("TRRx") program.

The sanofi-aventis Group supplies pharmaceutical products to U.S. Government hospitals, clinics, and pharmacies. In addition, we provide an extensive, dedicated customer service team to our Federal customers to ensure they receive the highest quality service. Government agencies purchase our products primarily under our FSS contract with the VA. The majority of the products we manufacture and sell to the Government are innovator prescription drugs covered by the VHCA and the terms of a Master Agreement between the sanofi-aventis Group and the VA, which implements the VHCA.

The Proposed Rule would allow the Government to demand, as a condition of selling certain pharmaceutical products on the FSS, that the manufacturers of those products contractually agree to a legal fiction in which purchases of medication from independent third parties are "deemed" FSS contract orders of supplies from the manufacturers. Because there are no actual sales transactions between the agency deemed to be ordering under the contract and the contractor, the contractor would be required to pay the agency a rebate measured by subtracting the FSS price from a commercial price point and remitting the difference. The VA would be entitled to collect a portion of the rebate for each prescription dispensed by a retail pharmacy to a Federal Agency Retail Pharmacy Program beneficiary as the Industrial Funding Fee on FSS sales, as if the prescription were ordered directly from the contractor.

The intended purpose of the special ordering clause, which would force contractors to recognize these deemed orders, is not to facilitate the acquisition process - in fact, the Proposed Rule creates new and significant administrative burdens for contractors and the FSS contract administrator. Rather, the purpose of the clause is to provide the big four agencies a contract basis to claim refunds from the FSS contractors on select transactions between beneficiaries and providers participating in the agencies' pharmacy benefit programs.[1] This proposal is unprecedented in law, unauthorized by statute, and inconsistent with the will of Congress. For the reasons discussed below, the sanofi-aventis Group strongly opposes the Proposed Rule and urges GSA not to promulgate it as a Final Rule.

[1] Payments to government agencies that rebate a portion of their pharmacy benefit expenditures, such as those paid under the Medicaid rebate program, must be specifically authorized by statute because these receipts fall outside the parameters of the Miscellaneous Receipts statute.

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1. **Implementation of the Proposed Rule**

As a preliminary matter, the Proposed Rule is unclear as to how it will be effectuated. It does not specify whether the clause will be inserted unilaterally in existing contracts or only in new solicitations and the next generation of Schedule 65 contracts. The Proposed Rule needs to clarify whether it is GSA's contention that the special ordering clause granting the big four agencies these unprecedented and extraordinary contract rights under the FSS program is required as a matter of law, and which law mandates this action. We know of no statute that requires FSS contractors to sell to authorized Schedule buyers indirectly through retailers. Even participation in an agency's prime vendor program discussed below is voluntary under the Prime Vendor Participation Clause of our FSS contract. On the other hand, if GSA's position is that the clause is permissive, the Proposed Rule should state that it is optional.

This is an important distinction because our FSS contract does not permit GSA or the VA to change the terms unilaterally. *See* FAR 52.212-4. Moreover, GSA may not enact laws and regulations intended to change the bargain and grant the Government more favorable rights under existing contracts. *United States v. Winstar Corp.*, 518 U.S. 839 (1996). After a very lengthy negotiation, the sanofi-aventis Group was awarded a five year FSS contract which established the terms under which we agreed to sell the products we offered under the contract to authorized ordering agencies. We offered specific products at specific prices to a narrow class of customer under specified terms. The effect of the special ordering clause fundamentally changes the deal that we negotiated with the VA.

2. **Flaws in the Depot Contracting System Rationale**

We urge GSA to consider these comments in evaluating the Proposed Rule's factual and legal foundation and rationale for authorizing use of the special ordering clause. Use of the clause to extend FSS prices to retail pharmacy reimbursement is based on the concept that the system by which the covered agencies provide a pharmacy benefit is a "depot" system of procurement, *i.e.*, a system of inter-related contracts through which agencies procure commodities from manufacturers under their FSS contracts. Recognizing, however, that there are no actual contracts between manufacturers, DoD, and the retail pharmacies that create a real procurement contracting system, and no actual contract orders placed directly (or indirectly through an agent) with the FSS contractors, the Proposed Rule is based instead on "deemed" orders through a "virtual" depot contracting system. In adopting this conceit to rationalize the clause, the Proposed Rule is predicated on fundamentally flawed conclusions and legal assumptions, inaccuracies, and factual misunderstandings, particularly with respect to the nature of prescription orders and the relationships of the parties to pharmacy benefit transactions. Moreover, we know of no law that permits agencies to order under the FSS through entities acting on their behalf without the consent of the seller and a contract authorizing the intermediary buyer to do so, and without the authorized buyer ordering directly and invoicing the

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agency at the contract price. In this regard, the special ordering clause conflicts with federal acquisition regulations governing FSS orders. *See* FAR 8.04(c)(3).

In order to qualify as a Federal Agency Retail Pharmacy Program, the agency must be authorized to provide pharmacy benefits in the form of a cost-share, and reimburse private sector pharmacies for the agency's cost share of the pharmacies' charge for prescriptions of "covered drugs" dispensed to agency beneficiaries. The agency must enter into a contract with a fiscal intermediary called a pharmacy benefits manager ("PBM") under which the PBM agrees to provide a network of retail pharmacies with whom they have payment agreements. Proposed Clause 552.238-XX(b). The PBM would be required to administer the benefit (coverage, deductibles, co-pays) and reimburse the network retail pharmacies in accordance with the benefit rules. The proposed clause contemplates that the drugs sold to the beneficiaries would be taken from the retail pharmacy's commercial stock acquired from its usual commercial sources, not a government source of supply. Proposed Clause 552.238-XX(d).

Under the proposed clause, the contractor would agree that the PBM's "instruction to its contracted or subcontracted retail pharmacy to fill a prescription for a health care beneficiary of the agency . . . shall be deemed an order placed against [the FSS] contract." Proposed Clause 552.238-XX(c). This "deemed" order will be "deemed" to constitute an order of an Executive Branch agency, which the contractor is "obligated to accept.". Proposed Clause 552.238-XX(e)(4). The purpose of the deemed order is to establish a basis for a "refund" under the FSS contract. The Federal agency administering the retail pharmacy program would track utilization of prescribed doses of covered drugs dispensed to beneficiaries through the retail pharmacy network and furnish the data to manufacturers so that the manufacturers can calculate and pay an amount to the agency based on the difference between a "benchmark" commercial price and the FSS contract price (negotiated Most Favored Customer price or the FCP for the drug, whichever is lower). Proposed Clause 552.238-XX(b). This rebate system is not based on any actual procurement from or charge by the manufacturer. Nor does it result in the agency actually obtaining the FSS contract price. In short, the clause requires manufacturers to agree to an elaborate fabrication.

a. Prescription Orders Are Placed by Program Beneficiaries, Not Payers

The first misconception incorporated into the Proposed Rule is that a Federal Agency Retail Pharmacy Program's PBM, in the TRRx plan, orders drugs offered on the FSS through an intermediary when it *instructs* its network retail pharmacies *to fill prescriptions* of plan beneficiaries. A "prescription order" is an order from a licensed health care professional to a licensed pharmacy authorizing it to prepare and dispense medication to a patient in the quantity and dosage ordered and to be administered in accordance with the instructions written in the order. How the patient pays the dispensing pharmacy for its service in filling the patient's prescription is between the patient and the pharmacy. When the patient is covered by a health plan that provides a pharmacy benefit structured as an insurance-type plan, as is the TRRx model

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for the Federal Agency Retail Pharmacy Program, [2] the PBM for the plan advises the pharmacy receiving the prescription order from the insured/beneficiary whether the plan will pay a portion of the pharmacy's charge for the prescription and how much, depending on the plan's coverage, formulary, co-pay structure, and deductible requirements.

Although the TRRx program uses managed care techniques such as the co-pay amount to influence the patient's decision on what to order, for example, whether the pharmacy may substitute a different medication or dispense as written, its PBM does not, as the Proposed Rule states, direct the retail pharmacy on behalf of the Government to fill or not fill the prescription. Regardless of whether the TRRx program or any similar Federal Agency Retail Pharmacy Program or its fiscal intermediary approves payment of the plan's share of the cost, the insured/beneficiary controls the purchase decision and directs the pharmacy to proceed to fill the prescription. Accordingly, there is no foundation for the Proposed Rule's conclusion that when the PBM for the Retail Pharmacy Program agrees to pay the dispensing pharmacy a share of the beneficiary's prescription cost, the Government is indirectly ordering the medication from the FSS contractor.

Describing a Federal Agency Retail Pharmacy Program as one involving an order from a fiscal intermediary for supplies is inconsistent with insurance and managed care principles and the legal relationships between providers, third party payers, and their beneficiaries. The language of the Proposed Rule in this respect appears intended to create one of several fictional underpinnings of the proposed special ordering clause needed to rationalize this action: In reality, in the TRRx model, the insured/beneficiary orders medication from a pharmacy and the PBM simply verifies the benefit and agrees to reimburse the pharmacy a share of the purchase price pursuant to a predetermined formula.

b. Prescription Orders Placed with Retail Pharmacies Cannot Be Ordered Directly From Manufacturers Under their FSS Contracts

The second erroneous assumption underlying the Proposed Rule is that prescription items covered by the "deemed" orders are contract line items offered by the contractors and that the orders could be performed directly by the contractors as well as through intermediaries. The products the sanofi-aventis Group sells to Government treatment facilities are the same commercial products we sell to pharmaceutical distributors and commercial health care providers, identified by a National Drug Code ("NDC") number. Each product we sell has a distinct NDC, and, as is common with commercial products, the individual items available for purchase and distribution to health care providers are referred to as Stock Keeping Units ("SKUs"). The VA refers to them as package units. Each product offered under the FSS is

[2] The TRRx program is an entitlement program designed like an insurance program to provide a pharmacy benefit at the point of sale by paying the service provider a portion of its charge to the insured customer.

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separately listed and priced by SKU as a contract line item, and each line item must be ordered by the NDC for that SKU.

Prescriptions direct pharmacies to dispense medication using standard pharmacy unit measurements for the form of the drug, for example, tablets, grams, or milliliters. Our commercial products are not sold in these quantities and there are no contract line items in our FSS contract for these units. Thus, even if the PBM could be considered the ordering entity instead of the person named in the prescription, the medication ordered is not what we offer for sale. The Proposed Rule creates an inherent conflict in that it purports to require us to recognize and "accept" orders of items we do not list on our FSS pricelist and actually sell under the contract, while simultaneously providing that the prescription orders are subject to the terms and conditions of the contract and that, in the event of a conflict between a prescription order and our contract, the contract shall control. Proposed Clause 552.238-XX(c). Thus, in most cases, the prescription orders will not be valid under the terms of the contract.

The concept of "deemed" orders in the Proposed Rule is intended to permit the big four agencies to treat third party prescription transactions as if they were direct orders with the FSS contractors. This goal is premised on the assumption that the agency could directly order medication dispensed to its beneficiaries under the contract without changing the basic terms of the contract. However, the premise is fallacious because we could not fill the "deemed" prescription orders directly. First, as discussed, we do not sell medication units commercially. Second, we are not licensed as a pharmacy, and we cannot, by law, fill actual prescription orders of health care professionals or distribute medication to patients under our FSS contract. Thus, unlike the provisions of the FSS contract that give us the option to sell our commercially packaged products directly and through the prime vendor, even if GSA accepts the premise that the agency is placing the prescription orders instead of its beneficiaries, the agencies could not order non-pricelist items and we could not, by law, fill and deliver those prescription orders.

c. The Retail Pharmacy Is Not a Purchasing Agent of the Government

The third erroneous assumption on which the Proposed Rule is based is that there is an agency relationship between the Government and network retail pharmacies that would support the notion that the pharmacies are akin to prime vendors, serving as purchasing agents and conduits of the agency's purchase transaction. Without these contractual relationships, there can be no depot "contracting system." There is no such entity recognized in federal procurement law as a "virtual" contracting system. Either there are interconnected contractual relationships forming a purchasing and distribution system or there are not. Here, there are not. Under the negotiated terms of our FSS contract, government treatment facilities may order contract line items directly from our purchasing department for delivery to a treatment facility or indirectly through the ordering agency's prime vendor. The agency's prime vendor is a wholesaler distributor under contract with the agency to purchase FSS contract line items from the schedule contractors on behalf of the agency's authorized ordering entities and deliver them to the

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agency's user facilities at the FSS contract price. We, in turn, have a distribution agreement with the prime vendor in which the parties agree we will charge the prime vendor the FSS price for contract line items ordered from it by our FSS contract customers.[3]

In the TRRx model, DoD has a contract with a fiscal intermediary to stand in the shoes of the agency and reimburse pharmacies providing prescriptions to its beneficiaries with government funds, just like the contractors that pay hospitals and physicians treating beneficiaries of federal health plans. The relationship between the PBM and DoD is that of a fiduciary, not a supplier. Indeed, GSA has not asserted that the agencies are ordering supplies from the PBM under its service contract. Nor is GSA asserting that the retail pharmacies are cost contractors sourcing supplies under the FSS and furnishing them to the Government at cost, because they are not.

To the contrary, retail pharmacies in the PBM's commercial network of providers have an agreement to accept a retail prescription price from the PBM for drugs dispensed to all the PBM's client plans. In the TRRx model, these retail pharmacies have no contracts with DoD under which they purchase product from FSS contractors on behalf of the agency and invoice the agency at the FSS price. The pharmacies purchase the drugs they use to fill their customers' prescriptions from commercial sources, and they charge the PBM their commercial network retail price. At no point in the distribution chain does the agency ever own the drugs ostensibly procured under the FSS contract. Furthermore, retail pharmacies are not our consignees or distribution agents. We have no agreements with them that authorize them to distribute our products to our customers at our customer's contract prices. We do not control their sales or the prices they charge their customers. In short, they are independent parties providing medication to beneficiaries.

When the actual relationships involved in the benefit payment system are understood, it should be evident that the retail pharmacy is the source of the prescription drugs paid for the PBM. It is not a prime vendor or intermediary under contract to acquire pharmaceutical supplies for the Government to use. There is no contract between the Government and the pharmacy directing it to purchase drugs from a particular source on behalf of the Government; we have no contract with the retail pharmacy authorizing it to sell our products to the Government at our FSS prices; and the drugs actually purchased and used by the pharmacy are never Government property. In sum, there is no system of contracts that connects the FSS contractor, the retail pharmacy, and a big four agency that would enable the agency to procure line items under the FSS contract through the pharmacy.

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[3] The charge to the prime vendor at the FSS price is accomplished through a charge-back credit system.

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d. There is No Contract Sale on which to Base an Overcharge Refund

The last illogical aspect of the Proposed Rule is that the FSS contractor is obligated to pay a refund under the contract as if it charged the agency an amount in excess of the contract price. As noted, the price the agency pays for a prescription order under a Federal Agency Retail Pharmacy Program is the price charged by the pharmacy reduced by the beneficiary's share, not a price charged by the manufacturer. An FSS contractor should not be deemed responsible for the price charged by a third party for a product the contractor happens to make. The proposed clause does not require the FSS contractor to refund the difference between the FSS contract price and the amount the pharmacy charged or the amount the reimbursing agency actually paid. Instead, it is requiring the contractor to "refund" the difference between the contract price and a price the contractor charged *a different customer*, which is then applied as an offset against the amount paid for the medication deemed to have been ordered under the FSS contract. However, when either the price charged or the price paid with Government funds is reduced by the amount rebated by the contractor, it does not produce the FSS contract price. Indeed, the price actually paid by the agency can be for less than the FSS contract price. There is simply no rational basis to call such a payment a "refund."

The sanofi-aventis Group respectfully submits that there must be some basis in reality for GSA to impose a rule that requires "refunds" from contractors. The use of a clause to coerce agreement to this fiction is improper rulemaking and a gross example of government overreach. This plan is particularly troubling in that pharmaceutical manufacturers are to be required to offer their covered drugs on the FSS or lose their Medicaid business and have no choice with respect to the clauses the Government includes. Under these circumstances, GSA should refrain from using that leverage to impose special rules that it does not impose on its other FSS contractors.

3. Neither the VHCA nor the FPASA Authorize Use of the Federal Supply Schedules as a Rebate Vehicle

The preamble to the proposed clause concludes that collecting refunds for sales made under a Federal Agency Retail Pharmacy Program would be "consistent" with the VHCA because the retail pharmacy program would qualify as a "virtual" depot contracting system. The preamble further concludes that two provisions of the Federal Property and Administrative Services Act ("FPASA"), 40 U.S.C. § 501 and 41 U.S.C. § 259(b), contemplate that an instruction by a federal agency to a retail pharmacy authorizing payment for a covered drug prescription ordered by a beneficiary of the agency can qualify as a "deemed order" by the agency from the manufacturer of the drug under the FSS contract through the retail pharmacy. It is not clear, however, whether GSA is authorizing this action under its own procurement authority based on its independent evaluation that the Schedule 65 contracts are part of a virtual depot contracting system, or whether it is relying on the VHCA as authority to extend negotiated FSS prices to the big four agencies through a virtual depot contracting system. In either case,

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however, sanofi-aventis Group respectfully disagrees for the reasons stated below that either statute authorizes GSA to promulgate the Proposed Rule.

There is no question that the Proposed Rule must be authorized by Congress. [4] It is "a fundamental principle of administrative law that agencies do not have the power to promulgate regulations absent a grant conferred by Congress."[5] Accordingly, there must be a reasonably clear nexus between the Proposed Rule and a delegation of the requisite authority by Congress to impose such a Rule. In this case, neither of the two statutes referenced in the Proposed Rule contemplate that GSA (or any other agency) can "deem" an agreement by an agency to pay a health care provider for medication dispensed to a program beneficiary to be an order by the agency under the prescription drug manufacturer's procurement contract. Moreover, contrary to the assertions in the preamble of the Proposed Rule, promulgating such a rule is clearly *not* consistent with congressional intent. Congress has repeatedly considered and rejected extension of federal contract prices to federal health insurance programs, including the TRICARE program on which the Proposed Rule is modeled. Thus, the Proposed Rule conflicts with and usurps policy-making in an area committed to the Legislature and on which the Legislature has spoken.

As noted below, the VHCA limits the price manufacturers of covered drugs can charge the big four agencies to the FCP when an agency "procures" covered drugs under an FSS contract or through a depot contracting system. It does not entitle an agency to "obtain" the FSS price on third party transactions through a rebate formula. Further, GSA cannot rely for the requisite authority on an interpretation of the VHCA by the VA that was never promulgated as a substantive rule and lacks any statutory effect.[6]

The other potential source of authority, the FPASA, authorizes GSA to procure goods and services for executive agency use. The FPASA does not authorize, or even contemplate, the imposition of price guarantees on third party transactions or the collection of "refunds" for products that are acquired from third parties. Moreover, GSA cannot permit non-Government buyers to order products (directly or indirectly) under FSS contracts without separate congressional authority. The FPASA is simply not applicable to non-procurement subsidy payments that reimburse retail pharmacies for a portion of the beneficiaries' purchase price.

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[4] *Chrysler Corp. v. Brown*, 441 U.S. 281, 303 (1979) (internal citations omitted).

[5] *Respect Inc. v. Comm. on Status of Women*, 815 F. Supp. 1112, 1123 (N.D. Ill. 1993) (court determined that the Department of Health and Human Services did not have authority to promulgate a regulation because the regulation in question was not within the contemplation of any existing statute).

[6] *Christensen v. Harris County*, 529 U.S. 576, 587 (2000), see also *Service Employees Int'l. Union v. GSA*, 830 F. Supp. 5 (D.D.C. 1993).

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a. The Veterans Health Care Act (38 U.S.C. § 8126) is Limited in Effect and Does Not Apply to Negotiated Prices or Benefit Payments to Retail Pharmacies

Underlying the Proposed Rule is the notion that the VHCA authorizes extension of FSS contract prices to purchases under a depot contracting system. The Proposed Rule indicates that the proposed special ordering clause is modeled after DoD's TRRx program. Several organizations have commented in connection with the TRRx program that the VHCA does not authorize extension of price controls to pharmacy benefit programs through a rebate mechanism. GSA was copied on most of those communications and we strongly support them.

As a condition of payment for covered drugs by the Government under the Medicaid program, the VHCA requires covered drug manufacturers to offer their products for sale on the FSS. It does not require that manufacturers sell indirectly to the Government through a depot contracting system. In addition, the VHCA caps the price manufacturers may charge for covered drugs the Government procures under the FSS contracts or through a depot system of procurement. The term "depot contracting system" and the definition of "depot" are used solely in connection with the application of the federal ceiling price to particular procurement vehicles. There is absolutely nothing in the VHCA that would mandate extension of FSS contract prices to the big four agencies through a depot contracting system. Likewise, the Master Agreement that we executed with the VA to implement the provisions of the VHCA does not require us to sell indirectly through a depot contracting system or to extend FSS contract prices to any authorized entity ordering through a depot contracting system.

Moreover, there is nothing in the VHCA or the Master Agreement that would authorize an agency to deem an order by a retail pharmacy with whom neither we nor the Government have a distribution arrangement to be a "depot." To the contrary, the Master Agreement interprets the term to mean a prime vendor or entity with whom we contract directly to distribute our products to the Government. Indeed, until the VA agreed that the TRRx program qualified as a depot contracting system, its long standing policy was that a direct contract between the Government agency and the commercial source of the drugs was necessary for the arrangement to be considered a depot. As discussed, in the Federal Agency Retail Pharmacy Program, the pharmacy is the source that receives the prescription order and agency payment and delivers the prescription to the beneficiary, but the agency has no contract with the pharmacy authorizing it to procure on its behalf. Nor does the agency or the pharmacy procure from the agency's prime vendor the drugs that the pharmacy uses to fill the prescriptions. The agency relationships and contractual connections needed to meet the statutory definition do not exist.

As stated in numerous comments concerning the TRRx program, the definition of depot in the VHCA requires the agency transactions be procurements. Here, the payments by the agencies with money authorized for expenditure under their retail pharmacy benefit programs are not procurements. They are not funds appropriated to acquire goods and services for their own use in treating patients, but direct subsidies paid to providers covering a share of the cost of

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goods and services they provide to third parties. The most fundamental flaw in the rationale for the Proposed Rule is that all direct Government payments are procurements. They are not.[7] The Government can meet the needs of its beneficiaries by providing for them itself or by subsidizing the costs they incur in the private sector. Thus, the Government can build and lease low cost housing and procure the supplies to carry out that mission, or it can pay rental subsidies directly to private landlords. Likewise, the Government can buy milk and provide it to needy children or it can provide direct subsidies to retail grocers that accept food stamps for milk. Here, the Government can provide pharmacy services directly or through contract pharmacies (like its mail order pharmacy) and procure pharmaceuticals needed by the pharmacy to carry out that function, or it can subsidize costs incurred by the beneficiaries at retail pharmacies. The pharmacy reimbursement payment is no more a "procurement" of drugs than is the food stamp redemption or the rent payment to the landlord.

Pursuant to the Chiles Act, 31 U.S.C. 6303-6305, which distinguishes between procurement and assistance relationships, it is improper for GSA to use a procurement contract as a vehicle for these agencies' prescription transactions, the principal purpose of which is to transfer something of value to a recipient in order to carry out the public purpose of support or stimulation authorized by a law of the United States, in this case, the TRICARE pharmacy benefit authorization, rather than acquiring property or services for the direct benefit or use of the United States Government.

b. The Proposed Rule Is Inconsistent with the Letter and Spirit of the VHCA

The Proposed Rule states that it is consistent with the VHCA, but provides no support for that proposition. In our view, both the express language of the statute and the legislative history make it very clear that Congress intended for the VHCA to be narrowly drawn and limited in effect. When enacted, provisions of the VHCA were designed to provide the big four agencies that actually procured drugs for use in their health care treatment facilities with a pricing system that acknowledged both the volumes and mechanisms of their drug purchases and the unique features of federal procurement. Certain system economies, and the closed-system nature of institutional purchasing for their own use, were believed to merit a discounted price. At the time of its enactment, the VHCA was intended to be limited to a small segment of the manufacturers' business represented by FSS and depot contract sales, which Congress estimated at 3%.[8]

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[7] FAR 9.403 defines subsidies and insurance as nonprocurement transactions. See also VA regulations which likewise give subsidies and insurance payments as examples of nonprocurement transactions. 38 C.F.R. 44.970. Transactions under the TRRx program also cannot constitute agency procurements because the PBM uses both appropriated and non-appropriated funds (Medicare trust fund) to pay the pharmacies for the prescription orders.

[8] S. Rep. 102-401, (1992), at 66.

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At the time of enactment, Congress recognized that DoD purchased pharmaceuticals from manufacturers under Distribution and Pricing Agreements that permitted direct delivery to DoD facilities instead of to a central government owned or operated warehouse. The definition of "depot" was intended to encompass the fledgling prime vendor system of procurement and direct distribution by manufacturers or their distribution agents to government user facilities, as well as delivery to traditional government depots.[9] However, it did not require manufacturers sell through "depots," nor did it require extension of sub-ceiling prices negotiated in accordance with FSS contracting rules to health care programs of the big four agencies.

Congress directed the provisions of the VHCA to two existing systems of procurement whereby the specified agencies purchased product for their own use following traditional federal procurement processes. It did not intend to expand this price-controlled system beyond the depot/centralized distribution system used by federal purchasers to acquire supplies. Nothing in the statutory language or legislative history envisioned the prices available under FSS contracts could reach transactions with uninvolved third parties, and, notwithstanding prior efforts by DoD and others to statutorily authorize application of federal contract prices to pharmacy benefit payments, no provision in any subsequent Act of Congress since has extended the procurement price controls to retail pharmacy reimbursement under any federal agency entitlement program.

That Congress intended to exclude a rebate mechanism for obtaining manufacturer "prices" on dispensed units under big four retail pharmacy programs is evident from its prior use of this mechanism in the Medicaid rebate statute. Under the drug reimbursement provisions of that statute, manufacturers rebate to the Medicaid program a percentage of the price of drugs dispensed to Medicaid beneficiaries by retail pharmacies. The only difference between that mechanism and the one contemplated by the Proposed Rule is the formula for measuring the rebate (*i.e.*, 15% of AMP or AMP less best price, whichever is more versus NFAMP or pharmacy price less FSS Contract Price). Because Congress enacted the Medicaid law prior to the VHCA, it was well aware of the mechanism used to obtain offsetting rebates for a benefit program, and could have authorized rebates on prescriptions covered by CHAMPUS (TRICARE's predecessor), but Congress did not.[10]

Finally, it should be noted that Congress did not intend for the statute to be applied expansively in future years. Section 601 of the VHCA expressly includes a provision that makes

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[9] At the time the VHCA was enacted, DoD purchased under DAPA agreements with manufacturers. If manufacturers delivered directly to DoD user facilities instead of through the prime vendor, which was optional, these sales would have been exempt from FCP. In order not to discourage use of the prime vendor, the definition of depot was expanded to include direct delivery to the user facilities.

[10] Congress recognized and distinguished a retail pharmacy benefit program in which the government agency finances a portion of the beneficiary's cost, such as the Medicaid system, from one in which the agency procures drugs for its own use. H.R. Rep. No. 102-384 (I) (1991), at 7. Congress also recognized the difference between FSS prices charged and FSS prices used as a basis for calculating rebates. S. Rep. No. 102-401 (1992), at 67.

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the principal enforcement mechanism inapplicable to subsequent amendments to Section 603. The Proposed Rule is attempting to do through regulation what Congress would not permit by statute.

c. The Federal Property and Administrative Services Act (40 U.S.C. § 501, 41 U.S.C. § 259(b)) Does Not Empower GSA to "Deem" Orders From Unauthorized Buyers as Contract Orders Under a "Virtual" Depot Contracting System

GSA suggests that it is authorized to promulgate the Proposed Rule under its general procurement authority. Section 201(a) of FPASA, 40 U.S.C. § 501, authorizes GSA to "procure and supply personal property and nonpersonal services for other executive agencies to use in the proper discharge of their responsibilities."[11] GSA has no authority to contract for the expenditure of public money for goods to benefit parties other than the Government unless specifically authorized by the Congress.[12] The purpose of FPASA was and remains "to provide the Federal Government with an economical and efficient system for....procuring and supplying property and nonpersonal services."[13] GSA's authority to contract for acquisition of property and services under the FPASA is limited by procurement laws and regulations applicable to civilian agencies and the policies of the Office of Federal Procurement Policy.

Section 309 of FPASA, 41 U.S.C. § 259(b), the other FPASA provision cited in the Proposed Rule, includes procedures established by GSA for the award of multiple award schedule contracts within the definition of "competitive procedures" under the statute."[14] Neither of the two cited FPASA provisions (nor any other FPASA provision) grant GSA power to acquire and supply property to third parties or to contract for the purchase of property on behalf of third parties even if the property is paid for in whole or in part with government funds. Otherwise, GSA could open up schedule contracts to grantees of federal agencies, recipients of federal loans, and other recipients of government benefits under federal entitlement programs by deeming their orders to be those of the agency, as long as the funds paying for the contract items came directly from a government account. Since GSA cannot contract to furnish prescription drugs to non-Government parties under the FPASA, it cannot promulgate a rule requiring contractors to rebate a portion of the payment for such transactions.

GSA's own order identifying those entities and organizations that are eligible to order supplies and services from FSS contracts acknowledges GSA lacks the authority to extend FSS

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[11] 40 U.S.C. § 501(b)(1)(A).

[12] General Accounting Office, *Principles of Federal Appropriations Law* 10-11 (2d ed. 1992)

[13] 40 U.S.C. § 471.

[14] 41 U.S.C. § 259(b).

prices to third party transactions.[15] The Order explains that organizations other than those identified[16] may be eligible pursuant to other sections of FPASA or "by reason of enabling statutory authority."[17] The GSA Order confirms that GSA lacks authority to "deem" beneficiary prescription orders placed with or by a retail pharmacy to be agency orders under the FSS and thereby allow third parties to access an FSS contract in the absence of a statutory mandate.

Further, the law does not empower GSA to deem purchases of products from merchants other than its contractors to be acquisitions of those products from the contractors simply because they manufactured them. Were that the case, GSA could promulgate a regulation allowing agencies to purchase any commercial items offered on the schedules directly from retail vendors at a higher price, deem those transactions to be orders from the manufacturer of the supplies, and demand refunds under the manufacturers' FSS contracts.

Here, GSA has combined both unauthorized actions into one rule in which there is no actual connection between the contractor and an agency procurement. It would permit agencies to treat beneficiary purchases of supplies from retailers using government funds as if they were agency acquisitions of supplies under the FSS. This is an extremely dangerous precedent. GSA could deem paper bought at any office supply store with a small business loan or a grant to be an acquisition from its paper contractor. The fact that the agency agrees to reimburse the retailer some or all of the purchase price with government funds instead of reimbursing the beneficiary makes no difference. The purpose of the agency's payment is to subsidize the beneficiary's purchase.

Moreover, even if the agency was "purchasing" from the retail pharmacy, the FSS contractor is not the source of supply. FPASA simply does not allow GSA to establish procedures that would deem the actual supplier and recipient of the agency's payment to be an intermediary ordering agent of the federal agency in the absence of a contractual relationship, or to deem assistance payment instructions to a third party vendor to be acquisition orders from an

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[15] GSA Order ADM 4800.2E ("GSA Order").

[16] GSA notes that FPASA authorizes it to "procure and supply personal property and non-personal services for executive agencies and other Federal agencies, mixed-ownership Government corporations as identified in the Government Corporation Control Act, the District of Columbia, and qualified nonprofit agencies for the blind or other severely handicapped for use in making or providing an approved commodity or service to the Government." GSA Order ¶ 3.

[17] *Id. Accord*, GSA Order ¶ 7 ("Organizations are eligible to use GSA sources of supply and services pursuant to the Property Act or other statutory authority"). See also FAR 38.101(c). However, an FSS contractor is not obligated to accept orders that are not "received from activities within the Executive Branch of the Federal Government." *See* I-FSS-103 Scope of Contract – Worldwide (July 2002). Thus, although approved cost reimbursement contractors can order from the FSS, the FSS contractor is not required to accept orders from those cost reimbursement contractors.

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FSS contractor. GSA is only authorized to establish ordering procedures for actual agency procurements under its contracts.

Additionally, the proposed GSAR clause is inconsistent with the Federal Acquisition Regulations ("FAR"). First of all, the "deemed order" concept in the proposed clause conflicts directly with the ordering requirements set forth in FAR 8.406-1 ("Order Placement"), which provides in pertinent part that an "ordering activity shall place an order directly with the contractor in accordance with the terms and conditions of the pricelists." Under the proposed special ordering clause, no order is placed "directly" with the contractor, either by the agency or by an ordering agent under contract with the agency. Indeed, the contractor would never receive an order referencing its FSS contract. Instead, the contractor would be required to treat the fiduciary's agreement to pay the retail pharmacy the agency's cost share as an "order." Moreover, as noted, the prescription orders are not in accordance with the FSS contract pricelist, because neither the medication unit or unit price match the FSS contract pricelist. Accordingly, the proposed GSAR clause directly conflicts with the FAR and constitutes an invalid exercise of agency authority.[18]

Furthermore, the Proposed Rule is unauthorized because its purpose is clearly not to improve the efficiency or economy of the process that GSA uses to procure or supply property or services for the use of executive agencies. To the contrary, the Proposed Rule instead requires adaptation of complicated new procedures to convert prescription medication utilization data into contract line item units, and systems to incorporate these pharmacy transactions into the contractors' sales and price reporting obligations. The reason for the Proposed Rule and for creating this cumbersome administrative process is to provide for rebate payments to offset agency entitlement programs expenditures, a power that GSA lacks under the FPASA. In short, the Proposed Rule would grant unprecedented access to FSS pricing by third parties that do not, in fact, order products or services from the FSS contractors.

4. The Proposed Rule Is Inconsistent with the TRICARE Reorganization Laws

The Proposed Rule states that application of the concept of "deemed" orders under a "virtual" depot contracting system as a means to extend FSS prices and price ceilings to the TRRx program is consistent with the TRICARE reorganization laws, in particular, Section 703 of the National Defense Authorization Act for FY 1999, Pub. L. 105-261, which directed DoD to

[18] FAR 1.302 ("Agency acquisition regulations shall be limited to – (a) Those necessary to implement FAR policies and procedures within the agency; and (b) Additional policies, procedures, solicitation provisions, or contract clauses that supplement the FAR to satisfy the specific needs of the agency.") In addition to the conflict with the FAR, the proposed GSAR clause fails to meet the second prong of FAR 1.302 because it would not further the needs of GSA (the agency promulgating the regulation). Instead, by its terms, the clause would benefit only the VA, DoD, PHS, and Coast Guard by entitling them to recover refunds on third party transactions. *See Service Employees Int'l Union v. Gen'l Servs. Admin.*, 830 F. Supp. 5, 9-10 (D.D.C. 1993) (GSA supplemental regulation held improper because it was contrary to a FAR clause and did not address a specific GSA need).

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incorporate best business practices of the private sector in its retail and mail order pharmacy system. However, the Proposed Rule circumvents the legislative intent because Congress rejected extension of price controls to the TRICARE program.

DoD proposed that legislation be enacted to bring procurements of pharmaceuticals through an authorized retail pharmacy network within the purview of Section 603 of the VHCA in order to obtain access to FSS prices for TRICARE retail pharmacy prescription expenditures. However, Congress declined to enact a law which would authorize use of the FSS contracts in this manner. Use of government price controls is not a practice used to manage retail pharmaceutical costs in the private sector. Private sector managed care organizations lower costs by, among other things, encouraging use of mail order, and using formulary structures and competition within therapeutic classes to obtain rebates on prescription utilization. As Congressman Stephen Buyer, the author of the TRICARE legislation, advised the VA, it was not the intent of Congress to permit extension of federal procurement prices to the Tricare retail pharmacy benefit program. Indeed, it was not until after Congress declined to provide the necessary authorization that DoD devised the "virtual depot contracting system." GSA's Proposed Rule thus conflicts with congressional intent.

5. The Proposed Rule Will Have Unintended Negative Consequences

Although some may refer to the system of establishing drug prices under the VHCA as "negotiation," this is erroneous terminology. The VHCA prices and discounts applicable to the FSS contracts are fixed by law and government controlled. There are significant penalties for manufacturers who decline to execute an FSS contract, or miscalculate the ceiling price. Congress recognized the unique nature of the VHCA, and thus carefully limited the statute's scope.

Requiring "refunds" on retail pharmacy benefit payments based on FSS contract pricing will not be in the best interest of TRICARE beneficiaries. Because DoD stands to realize a windfall in the form of manufacturer rebates applied to DoD's actual outlay in the retail pharmacy care setting where the beneficiary's cost-share is highest, this revenue to DoD encourages use of retail pharmacies over mail order and military treatment facilities, where the beneficiary's cost-share is substantially less. DoD charges nothing for prescriptions filled at MTFs and its beneficiaries need only pay a single co-pay for a 90 day supply of medication furnished by DoD's mail order contractor. By contrast, beneficiaries pay the same co-pay for a 30 day supply of medication from a retail pharmacy. Thus, rebates provide DoD a substantial incentive to steer its beneficiaries to the retail setting where their costs are highest and DoD's costs are lowest. Indeed, DoD has already begun steering beneficiaries away from the MTFs by reducing the availability of drugs in that setting and it has refused an offer from its mail order contractor to help increase use of mail order.

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Expansion of the VHCA price control system is unwise from the perspective of its potential impact on pharmaceutical prices for hundreds of millions of beneficiaries of private sector health insurance plans, federal employees' health plans, and government programs not encompassed by either the VHCA or the Medicaid statute, as well as approximately 47 million uninsured, who purchase prescription drugs on the retail market. The enactment of the VHCA was a direct result of such unintended consequences of the Medicaid rebate statue. After Medicaid rebates went into effect, government purchasers and others accustomed to receiving discounts or other kinds of favorable pricing found that their prices increased. This simple concept was the trigger for the VA and the DoD, to ask Congress for relief for their own drug procurements. There is no question that expanding the VHCA system will have the same kind of result for other programs, disadvantaging many millions more patients than the expansion theoretically might help.

In summary, we object to both the proposed rule, as well as to the inappropriate advance implementation of the proposal by the DoD, based on both legal and philosophical grounds. We strongly disagree that there is authority under the law for an extension of the contract mechanism of the VHCA to retail pharmacies or other third parties that are not direct parties to the contracts between the federal agencies and the manufacturers. We also disagree that, under any definition, the mechanism proposed constitutes a government procurement. Finally, we believe that this proposal is conceptually and philosophically contrary to the clear messages of Congress and the Executive Branch, over a number of years and through of series of legislative actions, that private sector competition-based price negotiations is the best and most appropriate mechanism and that government-controlled prices are economically unsound and not in the best interest of program beneficiaries over the long term.

We understand that DoD, having decided (contrary to GAO advice)[19] to separate drug coverage from other health care services for its TRICARE beneficiaries, wants to reach the most favorable financial position while maintaining the highest quality of care for beneficiaries. Similarly, the VA and other agencies named in the VHCA may wish to explore additional ways for beneficiaries to receive prescription drugs. We, and others in the pharmaceutical industry, are willing to work with the agencies to help achieve these goals, following best commercial practices, and have offered such assistance. For example, we are willing to discuss provision of competition-based rebates. We also are willing to assist agencies with expansion of the mail order programs in which we provide products at extremely favorable prices for distribution to beneficiaries who cannot access government pharmacies. The mail order cost for these beneficiaries is much less than the cost incurred at local retail pharmacies and we have pledged assistance in educating beneficiaries about the mail order program.

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[19] GAO Report to Congress, "Defense Health Care - Fully Integrated Pharmacy System Would Improve Service and Cost-Effectiveness," GAO/HEHS-98-176 (June 1998).

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We urge the GSA to withdraw this proposed rule, as we have urged the DoD to discontinue its approach. Pending litigation addresses the scope of the VHCA, and it is virtually inevitable that litigation will follow action by the GSA to finalize the Proposed Rule. During the pendency of such litigation, which could involve an extensive period of time, program beneficiaries will not be receiving the desired improved access to appropriately priced prescription drugs. In other words, while the agencies argue the technicalities of the law in court, a resolution that could benefit everyone will wait in the wings. We urge the agencies to take steps to work with manufacturers to address the matter, rather than propose new regulation that is contrary to both the law and the goals of the Administration.

Sincerely,

sanofi-aventis Group

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The Coalition
for Government
Procurement

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June 9, 2005

Ms. Lauriann Duarte
FAR Secretariat
General Services Administration
1800 F Street, NW
Room 4035
Washington, D.C. 20405

RE: GSAR Case 2005-G501

Dear Ms. Duarte:

The Coalition for Government Procurement is pleased to have this opportunity to submit comments on the above-referenced proposed rule issued in the April 12, 2005, *Federal Register*. The Coalition strongly opposes the proposed rule.

The Coalition is a multi-industry association of government contractors. We have over 330 members representing all commercial item market segments. Our members account for over 70% of the sales made through the Multiple Award Schedules program and about half of all commercial sales made annually to the federal government. Included in our membership is nearly every major pharmaceutical company selling through the VA Federal Supply Schedule program.

The Coalition has worked *with* officials in government for over 25 years for common sense acquisition rules. Specifically, we have worked with representative of GSA, the VA, DOD, OMB, and Congress over the ability of the DOD Tricare TRRx retail pharmacy program to have access to federal ceiling prices on pharmaceuticals for nearly three years. This is the issue covered by the proposed rule. We believe this proposal put forth by GSA is an attempt to implement via regulation a scheme that the VA and DOD have not been able to implement otherwise.

INTERPRETATION CONCERNS

We disagree that the proposed clause is consistent with Congressional intent under Section 603 of the Veterans Healthcare Act (VHCA) in the strongest possible terms. The Coalition has a long history of working with this statute

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and has had substantial opportunity to review the legislative history surrounding it. We believe strongly that this record shows that Congress did not intend to extend federal ceiling prices to pharmaceuticals the government, itself, never purchases.

The proposed rule covers pharmacy benefit plans of the "big four agencies" (VA, the Department of Defense, Public Health Service and the Coast Guard) that are structured as follows: the agency contracts with a pharmacy benefit manufacturer to act as its fiduciary agent and use government funds to pay a share of it network retail pharmacies' charges for prescriptions ordered by the plan beneficiaries in accordance with a predetermined cost-sharing formula. The proposed rule would require inclusion of a special clause that would deem prescription orders of medication units places by beneficiaries with retail pharmacies to be orders of federal agencies from manufacturers under their FSS contracts, while eliminating the contractors' rights under FAR 52.216-18, 52. 216-19 See 552.238-XX.

The rule mischaracterizes the transactions that occur at the pharmacy as "instructions to fill the prescriptions." The Pharmacy Benefit Manger (PBM) merely tells the pharmacy whether the beneficiary's federal plan will pay for it and how much. In fact, a prescription is an order from a physician to dispense drugs to a patient, and only the patient or a health care professional can order a pharmacy to fill a prescription. The decision on whether to fill the prescription at all, whether to fill it as written, or whether to substitute an equivalent drug is that of the beneficiary, not the agency or its fiscal intermediary. The agency and the PBM can only control whether the government or the beneficiary will pay for the prescription order and how much of the pharmacy charge will be shared.

In addition, the proposed rule ignores the fact that the retail pharmacy is the owner and source of the drug ordered and delivered to the beneficiary, and unlike procurements from the agency's prime vendor, there is no procurement contract with the retail pharmacy under which it promises to act as a conduit and sell goods to the government at the FSS price. In this construct, although the retail pharmacy receives the prescription order, fills it with product from its commercial stock, and is paid for it, it is not treated as the vendor from which FSS line items are sourced, but rather a "deemed" purchasing agent of the government.

The Coalition is concerned with this line of reasoning implicitly taken by GSA in the proposed rule. The pharmacy does not purchase the dispensed units ordered by the beneficiaries from manufacturers under the FSS contracts pursuant to a contract with the agency. It buys drugs from commercial sources, takes title, and uses them in its business, charging a negotiated price for dispensed units unrelated to the FSS contract price. Were it truly a purchasing agent, it would be contractually required to pass on the FSS contract price. Nor is the pharmacy a cost "subcontractor" entitled to buy off the FSS under existing FAR rules because it is not paid its acquisition cost plus a fixed fee for drugs used by the prime in performance of a government contract and is not subject to procurement rules applicable to cost contracts. A specific statute is necessary to mandate these particular FSS contractors pretend retail pharmacy sales of

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medications they manufacture are indirectly ordered from them on behalf of particular government agencies. Even the prime vendor program requires manufacturer consent.

The proposed rule forces certain FSS contractors, manufacturers of covered drugs, to agree as a condition of selling their products on the Federal Supply Schedule to the following contract term: approval by a fiscal intermediary of select agencies to pay one of its network health care providers a share of the provider's charge for an order placed by an agency program beneficiary shall be "deemed" an order by the agency from the manufacturer "through" the provider under the FSS contract, thereby granting the agency a contractual right to the contract price from the manufacturer on these third party payment transactions. Imposing these legal obligations on certain FSS contractors through the terms of their FSS contracts is unprecedented and unauthorized by any statute.

The Coalition also feels that the proposed rule is not clear in the statutory source of authority for granting the big four agencies the special contract rights contemplated, i.e., whether GSA's own statutes or the VHCA authorizes GSA to amend the GSAR in this manner. It is our belief that the applicable rules and statutes do not provide this authority. We are particularly concerned that the scope of the proposed rule is not limited to statutory ceiling prices available to the big four, but would require VA FSS contractors to extend their negotiated prices to particular federal program beneficiaries.

The Master Agreement and the pricing agreement required by the VHCA provide that actual contract prices are to be negotiated in good faith within the prescribed framework of the FAR, GSAR, VA acquisition regulations and other applicable rules. The FCP is merely a cap on those prices for the four agencies that procure pharmaceuticals for use in providing treatment at their facilities. The Coalition does not believe that GSA has the statutory authority to change the GSAR to grant select agencies special contract rights with respect to certain products of certain contractors under FSS contract rules and to read out rights to order limitations provided by the FAR. We know of no law that would permit GSA to "deem" the following: an order placed by a beneficiary is an order placed by an agency; an order placed with a retailer is an order placed with the contractor, and an order placed for medication units that are not described in the contract CLIN structure is an order of product units offered for sale by manufacturers under the contract.

We also believe that there is no authority to alter the bargain struck with respect to the negotiated terms of the contract. When manufacturers of covered drugs offer sub-ceiling prices under the FSS, the contracts are treated the same as all other FSS contracts for goods. Clearly, the VHCA does not deal with virtual depot contracting systems because, prior to the current effort to expand the original intention of the Act, there was no such concept. There is nothing in the VHCA that compels manufacturers to extend FSS prices to depot contracting systems.

An additional Coalition concern is that the proposed rule, itself, is inconsistent with GSA's own precedent setting determinations on schedule eligibility. The agency has previously, and

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consistently, rejected eligibility claims made on criteria to those substantially the same as those now put forth in the proposed rule. We believe strongly that the transactions between beneficiaries and retail pharmacies are not procurements. Rather, they are more closely identified as an agency or other entity receiving federal funds under a Cooperative Agreement, grant, loan, or other subsidy.

GSA has repeatedly rejected the interpretation that such transactions are procurements because the government can only use a procurement contract to pay for goods that are acquired for its own use. There is no procurement here. The transactions are payments by a fiscal intermediary reimbursing a retail pharmacy a cost share for providing a prescription to a beneficiary and have the same purpose as if the fiscal intermediary reimbursed the beneficiary who received the prescription the same amount if he or she paid the whole charge.

The Coalition believes that the nature of the transaction is that of a subsidy or insurance payment, which the FAR recognizes as a non-procurement transaction. See FAR 9.403. This distinction is similar to the difference between a voucher to obtain goods or services in the private sector and a procurement. A pharmacy dispensing a prescription to a Tricare beneficiary paid in part by DOD is no more ordering drugs for the Government than a landlord is leasing to the Government when HUD pays it a rental subsidy, or a retail grocer is ordering food for the Government when it accepts food stamps redeemed by DOA, or a private school is educating the Government when it accepts a tuition voucher from the student. In each of these cases the Government can choose to meet the health care, housing, educational or nutritional needs of its beneficiaries by directly providing them, in which case it can procure goods it needs to function as a provider (e.g., build and rent out low cost housing or buy and distribute

Case law supports an interpretation of the Tricare system as an assistance program rather than a procurement contract. For example, in *Partridge v. Reich*, a county fire department receiving federal funds under a contract between the Federal Emergency Management Agency ("FEMA") and the State allegedly violated the Veterans Readjustment Assistance Act ("VEVRA"), which required procurement contractors to implement affirmative action plans for veterans. The court determined that VEVRA did not apply to all agreements between the Federal government and third parties, but only to contracts for "procurement" for personal property and services for use by the government, concluding that an agreement to pay for emergency service between FEMA and the State was not a contract for "procurement" of services by FEMA. Likewise, the statutes authorizing GSA to execute procurement contracts with manufacturers do not extend to expenditures of federal funds for their products under non-procurement agreements.

In this case, DOD is making financial assistance payments to civilian pharmacies for prescriptions acquired not by DOD—which does not have a legal right to the dispensed drugs but by Tricare beneficiaries. There is no direct use by or for the Government, as required by the FAR. Accordingly, reimbursement of prescription claims is not a procurement of drugs by DOD.

By implementation of the Uniform Formulary multi-tiered structure in April 2004, the DOD moved toward creating a situation where pharmaceutical manufacturers were competitively incentivized to offer the agency more favorable pricing to achieve optimal formulary status. This is consistent with the best practices commercial model and the intent of the Congress. By the government setting prices through this proposed rule and a rebate mechanism it has effectively removed the market incentives to control costs. The Coalition feels that this is not in the government's best long-term interest.

On a final point in this area, the Coalition wishes to point out that throughout the government's attempts to expand the authority of the VHCA to include TRICARE retail pharmaceutical sales, the terms ***"rebate"*** and ***"discount"*** have been used interchangeably as if they were synonymous. This is not the case. A ***"discount"*** is an upfront reduction in purchase price normally based on favorable trade terms or preferred customer status. The Federal Ceiling Price described in the section 603 of the VHCA is a ***"discounted"*** price. A ***"rebate,"*** however, is a backend return of a proportion of the original purchase price usually based on volume of sales. The VHCA does not authorize or discuss ***"rebates."*** However, ***"rebates"*** are what are being proposed by this GSA rule.

OPENING THE SCHEDULE TO BENEFICIARIES

The proposed rule deems orders of supplies by federal beneficiaries placed with retailers for the personal use of the beneficiaries to be orders from the schedule contractors. Yet, neither beneficiaries nor retailers are authorized users of the schedule contracts. By authorizing indirect use through "deemed orders," the proposed rule authorizes use by entities that could not place orders directly. The Coalition does not believe that the VHCA authorizes this scheme. Similarly, we do not believe that the laws and regulations governing the Multiple Award Schedules program allow for these types of procurements. As such, the Coalition believes that the proposed rule is fundamentally incompatible with the intent of the schedules program. Taken to its next step, GSA could just as easily open up the MAS program to deemed orders by grantees, loan recipients, or others entitled to have federal agency funds pay for goods.

We see this as a very dangerous precedent that would undoubtedly have a substantial and deleterious impact on the government's largest commercial item procurement method. The ramifications of this potential are huge. We strongly recommend steering away from this course as the agency reconfigures itself and continues to respond to criticism that some customers already make improper use of GSA contracts.

IMPACT ON OFPP ACT

The Office of Federal Procurement Policy Act (OFPPA) incorporates the Chiles Act, 31 U.S.C. 6303-6305, which prohibits agencies from using procurement contracts for transactions when the purpose is the acquisition of supplies for the benefit and use of parties other than the Government. That is why we have grants, cooperative agreements, assistance agreements, and other transactions. Here, the drugs are not entirely paid for by the agency and they are not being used by the agency. It is contrary to law and federal procurement policy to allow GSA to use the FSS to cover assistance transactions.

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IMPLEMENTATION CONCERNS

Aside from the fact that there is no statutory authority for this proposal, the Coalition is also very concerned over the manner in which GSA would implement the proposed regulatory change, even if some heretofore unknown authority does exist, on established contracts already in existence. Certainly the change contemplated by the proposed rule greatly alters current contracts. Even if GSA has the discretion to insert new clauses in new contracts and solicitations, without clear statutory authority to impose such new obligations on the contractors during the base term, the proposed rule's clause will be a cardinal change. We see no alternative other than negotiating brand new contracts based on this new reality with every pharmaceutical contractor and ending all current contracts. This would be a very substantial undertaking as the contracts currently in place took several years to negotiate and award.

We see this as a substantial burden to contractors, especially small businesses. It does not seem that this impact was adequately assessed in the *Federal Register* notice. We request that an appropriate small business impact statement be prepared before any formal rule goes forward and that the comment period be extended to allow small firms adequate opportunity to comment on the resultant findings.

CONCLUSION

The Coalition believes that the proposed rule is not in the best interest of government, industry, or Tricare beneficiaries. We believe it is essentially a political attempt to provide coverage for a program badly wanted by DOD to meet now-expected budget parameters, but which fails to pass regulatory or statutory muster. It simply does not provide adequate, or in our view legitimate, legal justification to achieve the desired end. We urge the withdrawal of the rule and recommend that DOD and the VA seek other means to achieve their end in cooperation with their industry partners.

Sincerely,

Larry Allen

Larry Allen
Executive Vice President

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Wyeth

June 13, 2005

BY HAND DELIVERY

Ms. Laurieann Duarte
General Services Administration
Regulatory Secretariat (VIR)
1800 F Street, N.W., Room 4035
Washington, D.C. 20405

Re: GSAR Case No. 2005-G501

Dear Ms. Duarte:

On April 12, 2005, the General Services Administration ("GSA") published a Proposed Rule that would create a new General Services Administration Regulation ("GSAR") clause entitled "Federal Agency Retail Pharmacy Program Supply Schedule."[1] This new clause apparently will be inserted in Group 65 Federal Supply Schedule ("FSS") contracts and would allow the Department of Defense ("DoD"), the Department of Veterans Affairs ("VA"), the Coast Guard and the Public Health Service ("PHS") (collectively, the "Big Four" agencies) to obtain rebates on purchases by their beneficiaries through a qualifying "Federal Agency Retail Pharmacy Program." Wyeth Pharmaceuticals ("Wyeth") appreciates the opportunity to comment on the Proposed Rule.

Wyeth Pharmaceuticals, Inc., a subsidiary of Wyeth, is one of the world's largest research driven pharmaceutical and health care products companies with leading products in the areas of women's health, cardiovascular disease, central nervous system, inflammation, hemophilia, oncology, and vaccines. Wyeth supplies pharmaceutical products to U.S. Government hospitals, clinics, and pharmacies. Wyeth has negotiated contracts of several different types with the VA and the DoD and has offered such products as Protonix, EffexorXR®, Prempro®, and Premphase® at prices below the Federal Ceiling Price ("FCP"). All of the products that we manufacture and sell to the Government are covered drugs under the VHCA and the terms of a Master Agreement and a Pharmaceutical Pricing Agreement executed by Wyeth and the VA. Effective November 1, 2004, after a lengthy negotiation, we renewed our Schedule 65 FSS contract for a five-year

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1 70 Fed. Reg. 19,045 (Apr. 12, 2005).

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term, through October 31, 2009.[2] Our FSS contract does not contemplate rebate payments on Federal Agency Retail Pharmacy Program sales. Nor does it require us to make our FSS price available for any of the products that we sell for orders made by non-executive agencies. Thus, implementation of the Proposed Rule would seek to fundamentally alter the bargain that we recently struck with the VA.

Wyeth has reviewed the comments submitted today by the Pharmaceutical Research and Manufacturers of America ("PhRMA"), a trade association of which Wyeth is a member. As described below, Wyeth agrees with PhRMA that the GSA is not authorized under any statute to implement the Proposed Rule, and that the Proposed Rule would create a number of operational issues that would make the rule impractical, if not impossible, to implement. We incorporate those comments herein by reference and offer the comments below to supplement the comments submitted by PhRMA.

The GSA Does Not Have Statutory Authority to Implement the Proposed Rule

The Proposed Rule provides that, if a Federal agency establishes a "Federal Agency Retail Pharmacy Program," meaning a retail pharmacy program under which: (a) the Federal agency enters into a contract with a Pharmacy Benefit Manager (PBM) to administer a retail pharmacy network; (b) the PBM issues payments for drugs dispensed in retail pharmacies from an appropriated fund account; and (c) the Federal agency provides quarterly utilization reports to manufacturers of covered drugs; the Federal agency will be entitled to collect "refunds"[3] from manufacturers designed to approximate the FSS price for covered

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2 FSS Contract No. V797P-5775x (Nov. 1, 2004).

3 The Proposed Rule uses the term "refund" instead of rebate, but that is a misnomer. Use of the term "refund" presupposes that the Government has overpaid Wyeth for a particular drug and is simply requiring Wyeth to pay back the amount of the overpayment. In reality, the Proposed Rule establishes a rebate mechanism, similar to the system established under the Medicaid Rebate Act, under which manufacturers are required to make rebate payments after the end of a reporting period. Notably, as described below, the Veterans Health Care Act establishes a discounted price for covered drugs procured by the Big Four agencies under a depot contracting system or an FSS contract. It neither establishes nor supports the establishment of a back-end rebate scheme of the nature contemplated by the Proposed Rule.

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drugs. The Proposed Rule cites Section 603 of the Veterans Health Care Act of 1992 ("VHCA"), 38 U.S.C. § 8126, and Sections 201(a) and 309 of the Federal Property and Administrative Services Act ("FPASA"), 40 U.S.C. § 501 and 41 U.S.C. § 259(b), as primary support for this proposal. The GSA's reliance on these provisions is misplaced.

The VHCA is a pricing statute. It requires manufacturers of "covered drugs," such as Wyeth, to enter into agreements with the VA under which the manufacturer agrees to make a discounted price (the FCP) available to the Big Four agencies for covered drugs that are "purchased under depot contracting systems or listed on the Federal Supply Schedule."[4] The VHCA proceeds to define the term "depot" narrowly, as:

> a centralized commodity management system through which covered drugs procured by an agency of the Federal Government are –
>
> (A) received, stored, and delivered through –
>
> (i) a federally owned and operated warehouse system, or
>
> (ii) a commercial entity operating under contract with such agency; or
>
> (B) delivered directly from the commercial source to the entity using such covered drugs.[5]

Our Master Agreement with the VA defines the term "depot" by reference to the statutory definition and further notes that the term "depot" will be interpreted "to include Prime Vendor contractors of the Federal Government and direct vendor

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[4] 38 U.S.C. § 8126(a)(2).

[5] 38 U.S.C. § 8126(h)(3).

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distribution arrangements."[6] Neither the VHCA nor our Master Agreement authorizes the Government to collect rebates on non-procurement transactions, such as reimbursement transactions, where there is no procurement of covered drugs by the Government or a prime vendor. Yet, that is precisely what the Proposed Rule contemplates.

In the circumstances described by the Proposed Rule, there is no procurement of covered drugs from Wyeth by a Federal agency or a Federal agency's authorized purchasing agent (such as a prime vendor). Wyeth has no contract with a Federal agency or a purchasing agent of a Federal agency under which we have agreed to make our covered drugs available in retail pharmacies at the FCP or the FSS price. Instead, we have contracts with commercial wholesalers under which we have agreed to furnish the drugs that retail pharmacies ultimately dispense to Federal agency beneficiaries (as well as to beneficiaries of commercial plans). Those contracts contain terms and conditions, including pricing and quantity terms, that we have negotiated directly with wholesalers. The Federal Government is not a party to those commercial arrangements. Because a "contract" between Wyeth and the Government is a necessary component of a depot contracting system and that component is absent here, a Federal Agency Retail Pharmacy Program would not qualify as a depot contracting system under the VHCA.[7]

Recognizing that a procurement contract is a prerequisite to a procurement[8] and that a procurement is a necessary part of a depot contracting system under the VHCA, the Proposed Rule asserts that a Federal agency's instruction to a retail

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[6] Master Agreement, § I.F.

[7] The VA previously determined that the VHCA did not extend to the DoD's retail pharmacy program. *See* Letter from Melbourne A. Noel, Jr., Office of General Counsel, Dep't of Veterans Affairs, to "Dear Manufacturer of Covered Drugs,"(Oct. 7, 1996) ("Dear Manufacturer Letter"). Subsequently, the DoD sought an amendment to the VHCA that would have included its retail pharmacy sales within the scope of the VHCA's price controls. Congress did not promulgate the DoD's requested amendment.

[8] 31 U.S.C. § 6303 (the Government must use procurement contracts when the principal purpose of a transaction is to acquire property or services for the direct benefit or use of the Government).

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pharmacy to fill an order for a Federal agency beneficiary constitutes a "deemed order" by the Federal agency under our FSS contract. In this fashion, the Proposed Rule attempts to deem our FSS contract as the "procurement contract" that authorizes the collection of rebates on retail pharmacy sales. The "deemed order" requirement, however, is also inconsistent with law.

The GSA derives its authority to implement the FSS contracting system from FPASA. In particular, FPASA authorized the GSA to "regulate the policies and methods of executive agencies with respect to the procurement and supply of personal property and nonpersonal services."[9] As noted, the Proposed Rule does not relate to Federal procurement of covered drugs from Wyeth. Instead, it involves Federal reimbursement of claims made by retail pharmacies in connection with orders placed by an agency beneficiary. Consistent with FPASA's limitation to Federal procurement, our recently negotiated FSS contract specifically provides that Wyeth "is not obligated to accept orders received from activities outside the executive branch."[10] Similarly, our FSS contract also provides that our participation in the Government's prime vendor program is voluntary.[11] Because the Proposed Rule addresses Federal reimbursement transactions and not Federal procurement, FPASA does not authorize the Proposed Rule.[12]

The Proposed Rule is also flawed because it is inconsistent with the Federal Acquisition Regulations ("FAR"). The FAR specifically requires that orders under our FSS contract be placed "directly with the contractor in accordance with the terms and conditions of the pricelists."[13] The only "order"

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[9] H.R. Rep. No. 670, 81st Cong., 1st Sess. (1949), reprinted in 1949 U.S. Code Cong. & Admin. News 1475.

[10] I-FSS-103 SCOPE OF CONTRACT – WORLDWIDE (JULY 2002) (VARIATION).

[11] *See* "Prime Vendor Participation" clause, FSS Contract No. V797P-5775x at 85. We have agreed to participate in the Government's prime vendor program.

[12] Moreover, the FAR makes clear that reimbursement transactions, such as insurance and subsidies, are non-procurement transactions. Federal Acquisition Regulation ("FAR") § 9.403 (2005).

[13] FAR § 8.406-1 (2005) (emphasis added).

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contemplated under the proposed Federal Agency Retail Pharmacy clause, however, would be placed by the individual beneficiary, who would obtain a prescription for medicine from a licensed physician and seek to have that prescription filled in the retail pharmacy. Assuming that it received authorization from the Federal agency's PBM, the retail pharmacy then would fill the beneficiary's order from its own commercial inventory of drugs acquired either from us or from a wholesaler. The retail pharmacy would not fill the beneficiary's prescription order from an inventory of covered drugs purchased by the Federal agency from us under our FSS contract. Thus, no order is placed directly under our FSS contract. And, the order that is placed by the beneficiary in the retail pharmacy would not comport with our FSS price list (which is based on stock keeping units and national drug codes, whereas the size of an individual beneficiary's prescription order is determined by the prescribing physician) and the other terms and conditions of our FSS contract. For these reasons, the Proposed Rule is inconsistent with the FAR ordering provisions and therefore is invalid.

Finally, as discussed thoroughly in PhRMA's comments, even the GSA's own guidance confirms that, for a new entity to be granted access to the FSS, authority must be established pursuant to a statute (or a regulation properly issued pursuant to a statute).[14] Here, as described above and in PhRMA's comments, no statute or validly promulgated regulation authorizes the Proposed Rule. Accordingly, the Proposed Rule is not consistent with the GSA's own guidance and should not be implemented.

Issues Concerning the Application of the Proposed Rule to Wyeth

As noted, Wyeth has an executed FSS contract that is in place through October 31, 2009. That contract resulted from a series of negotiations. One of the terms of our FSS contract, FAR 52.212-4, provides that "changes in the terms and conditions of this contract may be made only by written agreement of the parties."[15] Wyeth has not agreed in writing to change its FSS contract to include the proposed new clause, 552.238-XX. For this reason, to impose the clause

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[14] GSA Order ADM 4800.2E (Jan. 3, 2000).

[15] FSS Contract No. V797P-5775x at 2.

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unilaterally, without negotiating appropriate consideration for Wyeth, would be a breach of our contract.

Additionally, and for similar reasons, the GSA should confirm that compliance with the Federal Agency Retail Pharmacy clause would be voluntary. As discussed above, the Proposed Rule would deem an instruction by a Federal agency (or its PBM) to a retail pharmacy to dispense covered drugs to an agency beneficiary to constitute the equivalent of a direct order by the Federal agency under our FSS contract. Under our FSS contract, we are not required to fill orders that are not directly made by a Federal agency. Our FSS contract is limited in this fashion because the GSA's authorizing statutes do not permit the GSA to mandate that we sell products under our FSS contract to entities that are not executive agencies.[16] Accordingly, Wyeth understands that compliance with the Federal Agency Retail Pharmacy clause would be on a voluntary basis. If the GSA believes that compliance with the proposed clause would be mandatory, then we respectfully request that the GSA articulate the basis for its position and allow Wyeth an opportunity to respond.

Issues Concerning the Industrial Funding Fee

The Proposed Rule would require Wyeth to pay the Industrial Funding Fee ("IFF") to the VA for retail pharmacy sales.[17] The purpose of the IFF is to compensate the VA for its administration of the FSS contracts. However, with respect to retail pharmacy sales, the VA would not play any administrative role. Rather, as described by the Proposed Rule, the Federal agency administering the retail pharmacy program would be responsible for collecting utilization data and for working with FSS contractors in the rebate payment process. Because the VA would not incur any administrative costs in connection with a retail pharmacy program implemented by a Federal agency other than the VA, the VA is not entitled to the IFF on retail pharmacy sales.

Additionally, Wyeth embeds the IFF payment within its FSS prices. The Proposed Rule provides that the rebate calculation would be based on the

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16 40 U.S.C. § 501.

17 70 Fed. Reg. at 19,051 (552.238-XX(i)).

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difference between the non-FAMP (or the actual price charged to the wholesaler or retail pharmacy chain) and the lower of the FCP or the "negotiated FSS price." The use of the term "negotiated FSS price" creates an ambiguity as to how the Proposed Rule would differentiate (if at all) between FSS contract holders that embed or absorb the IFF payment. Wyeth respectfully requests that the GSA clarify that, for those companies that embed their IFF payments within their FSS prices, the price to be used in the rebate formula is the FSS price that includes the embedded IFF payment (*i.e.*, the negotiated price plus 0.5%).

Right to Audit

The Proposed Rule would require Wyeth to rely on utilization data collected by a Federal agency and provided to Wyeth in the form of flat file layout reports to calculate the rebate amount owed.[18] It is on the basis of the data provided to us that we are directed to determine the amount of the rebate owed and to pay the IFF. With respect to orders placed directly under our FSS contract, we are responsible for reporting our quarterly sales to the VA, and the VA is entitled to audit Wyeth to verify the accuracy and completeness of Wyeth's sales reports.[19]

Wyeth should have the same right to audit the Government's systems in the circumstances contemplated by the Proposed Rule, where our IFF and rebate calculations will be based on information compiled and provided by the Federal agency implementing the retail pharmacy program. Under the rule as written, we would not have any visibility into the Government's data collection systems. Moreover, it is not possible for us to track utilization of our covered drugs by Federal agency beneficiaries in retail pharmacies because we are not a party to retail pharmacy transactions with their patrons. Accordingly, we recommend that, if the GSA is to proceed with the Proposed Rule (which it should not do), a subsection be added to the clause that would afford FSS contractors, such as Wyeth, a discretionary right to audit the Federal agency's systems on a quarterly basis to ensure the accuracy of the utilization data compiled by the Government.

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[18] 70 Fed. Reg. at 19,050-51.

[19] AS13, Examination of Records by VA (MULTIPLE AWARD SCHEDULE) (FEB 1998).

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Issues Related to the Rebate Formula

The clause established in the Proposed Rule would require FSS contract holders to pay rebates amounting to the difference between the non-FAMP for a covered drug (or the actual price paid by a wholesaler or pharmacy if known and auditable) and the lower of the FSS price or the FCP for the drug.[20] Wyeth offers dual pricing for the drugs that it offers on its FSS contract. Some of the prices that we offer are sub-ceiling, meaning that our FSS price for a covered drug is lower than the drug's FCP. Under the Proposed Rule, we would be required in these circumstances to use the FSS price to calculate the amount of the rebate that is due. We are not aware of any provision in the VHCA (or any other statute) that would authorize use of the FSS price as a benchmark for determining rebates due under a depot contracting system. We therefore request that the GSA explain the statutory basis for the Proposed Rule's use of the FSS price as the basis for calculating rebates that would be due to the Federal agency.

Moreover, the Proposed Rule would require Wyeth to pay the full amount of the rebate that is due during the pendency of a dispute over the amount of the rebate owed. In our view, the GSA should adopt the approach taken under the Medicaid Rebate statute. In that context, in the event of a dispute over the amount owed, we are required to pay the portion of the rebate amount that is not disputed. The balance is due only after the dispute is resolved. For consistency purposes, a similar approach should be adopted here.

Finally, the proposed rebate formula would not result in the Government paying either the FSS price or the FCP for each covered drug dispensed through a Federal Agency Retail Pharmacy Program. Nor is the rebate formula tied in any way to the amount that the Federal agency would pay to the retail pharmacy for our covered drugs, which is the difference between the retail pharmacy price for our

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[20] 70 Fed. Reg. at 19,050 (552.238-XX(b)). This subsection of the proposed clause is unclear as to whether Wyeth would have discretion to choose the benchmark price (either non-FAMP or the price charged to a wholesaler or retail pharmacy chain). Under the DoD's retail pharmacy program, it is contemplated that manufacturers will be entitled to make that election. We recommend that the GSA modify subsection (b) of the proposed clause to make clear that the choice to use the non-FAMP or the price charged to a wholesaler or retail pharmacy chain is "at the discretion of the FSS contract holder."

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covered drug and the beneficiary's cost share, plus a dispensing or administrative fee. Instead, the rebate formula in the Proposed Rule (which uses the non-FAMP or the price charged to a wholesaler or retail pharmacy chain as the benchmark price) is designed, at best, to enable the Federal agency to approximate the amount of the FCP or the FSS price for our covered drugs. Neither the VHCA nor any other law of which Wyeth is aware supports the Proposed Rule's rebate formula. We respectfully request that the GSA explain in full its rationale for the rebate formula that it included in the Proposed Rule.

Conclusion

Wyeth believes that the Proposed Rule is not a proper exercise of authority by the GSA. The DoD's TRRx Program, on which the Proposed Rule appears to be modeled, is currently the subject of litigation, the resolution of which may affect the validity of the Proposed Rule. We strongly urge that the Proposed Rule be withdrawn and encourage the DoD and the VA to seek alternative methods to achieve their goals. At a minimum, we believe that the GSA should not take any action on the Proposed Rule until the pending litigation is resolved. Wyeth appreciates the opportunity to submit comments on the Proposed Rule.

Sincerely,

Kevin F. Brady

2005-G501-4

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June 13, 2005

VIA ELECTRONIC MAIL AND FACSIMILE

David A. Drabkin
Senior Procurement Executive
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General Services Administration
Regulatory Secretariat (VIR)
1800 F Street, N.W.
Washington, D.C. 20405

Re: GSAR Case 2005-G501: Proposed Rule
Regarding Federal Agency Retail Pharmacy Program

Dear Mr. Drabkin :

We appreciate the opportunity to submit comments on behalf of several of our pharmaceutical manufacturer and biotech clients in response to the Proposed Rule with comment period ("Proposed Rule"), published by the General Services Administration ("GSA") in the April 12, 2005 Federal Register, regarding the Federal Agency Retail Pharmacy Program (70 Fed. Reg. 19045-19051). We respectfully offer the following comments.

In summary, our concerns and issues fall within three areas. We believe that the Proposed Rule is inconsistent with existing law and that certain agency determinations fundamental to the Proposed Rule are incorrect and improperly issued. Irrespective of the legality of the program, the existing Federal Supply Schedule contract includes a number of clauses that arguably are in conflict with this Proposed Rule. Finally, we have identified several issues regarding implementation of the substantive requirements of the Proposed Rule.

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I. Legal Issues

As a preliminary matter, we note that there is significant debate whether this program is legal or, instead, is contrary to law, specifically Section 603 of the Veterans Health Care Act ("VHCA") of 1992, codified at 38 U.S.C. § 8126. In fact, a fundamental premise underlying the proposed regulatory scheme is currently subject to legal challenge. *See The Coalition for Common Sense in Government Procurement d/b/a/ The Coalition for Government Procurement v. Nicholson,* No 05-7130 (Fed. Cir., filed March 24, 2005).

The Proposed Rule refers to and relies upon in several instances certain legal determinations or conclusions regarding the proposed program structure (*i.e.*, access to Federal Supply Schedule ("FSS") pricing and procedures for the Department of Defense ("DoD") "virtual depot system" utilizing "contracted" retail pharmacies as part of a centralized commodity management program or other similar systems developed in the future). Each of these determinations may be contrary to law. Key references are set forth below:

- This rulemaking is consistent with the authority provided by 38 U.S.C. § 8126 to acquire drugs at the statutorily provided discount through use of a depot contracting system. 70 Fed. Reg. at 19046.

- By letter dated October 14, 2004, drug manufacturers were advised by the Acting Executive Director, Department of Veterans Affairs (VA) National Acquisition Center that] the VA Secretary has determined that DoD's TRICARE Retail Pharmacy Program was a centralized pharmaceutical commodity management system that met the definition of "depot" contracting system as set forth in 38 U.S.C. § 8126. 70 Fed. Reg. at 19047.

- The Federal Agency Retail Pharmacy Program procedures, including pricing procedures, and those in this clause, are consistent with 38 U.S.C. § 8126. *See* 48 CFR 552.238-XX (b), 70 Fed. Reg. at 19050.

As you likely know, on March 24, 2005, The Coalition for Common Sense in Government Procurement d/b/a The Coalition for Government Procurement ("the Coalition") filed a petition for review of the final order issued by the VA on October 14, 2004. In that order, the VA directed manufacturers of "covered drugs" to "refund" to DoD the difference between the price the manufacturers charged their commercial customers and the "Federal Ceiling Price," for prescriptions dispensed to DoD beneficiaries by retail pharmacies for which DoD pays the cost. Until a final judicial determination is made in the lawsuit, it is inappropriate for the GSA to rely upon the VA's determinations as the basis for the Proposed Rule. Consequently, no further regulation should be promulgated pending resolution of such legal challenge.

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Irrespective of the pending lawsuit, the Federal Agency Retail Pharmacy Program and the contemplated pricing and procedures are not authorized by or consistent with the VHCA statutory scheme. Under the statute, manufacturers are required to agree not to charge the DoD or VA (or the Coast Guard or Public Health Service) a price higher than the Federal Ceiling Price for covered drugs procured through either FSS contracts or a "depot contracting system." The TRICARE Retail Pharmacy Program fails to meet several aspects of the statutory definitions.

Drugs purchased by TRICARE beneficiaries are not "procured by a federal agency" as required by 38 U.S.C. § 8126. Here, the only procurements of drugs are those purchases made by wholesale distributors, retail pharmacies and TRICARE beneficiaries. Here, DOD is seeking rebates on purchases made by customers (who are TRICARE beneficiaries) from retail pharmacies. While it is true that DOD (through a Pharmacy Benefits Manager ("PBM") ultimately may reimburse the retail pharmacy for the amount negotiated by the PBM, DOD does not have a contract to procure the drugs from the retail pharmacy, the wholesaler or anyone else. Because DOD only is entitled to discounts on drugs "procured" by it, it has no legal right to demand discounts on purchases that it does not make, *i.e.*, purchases made by other parties. Also, the fact that DOD (through the PBM) reimburses the retail pharmacies does not constitute a procurement. Reimbursement is distinct from procurement. Similarly, DOD's verification of eligibility of the TRICARE beneficiary to purchase drugs is not a procurement.

The TRICARE Retail Pharmacy Program system is not a "depot." In addition, the VHCA only applies to drugs procured through the FSS or through a depot. Depot is defined in the VHCA. *See* 38 U.S.C. § 8126(h)(3). That definition provides two means by which a system can qualify as a depot. Notably, both means require a procurement by an agency—a requirement that is not met here.

However, even assuming that the procurement by an agency requirement were met, the TRRx network still fails to meet the "depot" definition. To meet the statutory definition of a depot, the drugs must be "received, stored, and delivered through . . . a commercial entity operating under contract with [DOD]" (or a "federally owned and operated warehouse system"). *Id.* In this case, the drugs will be stored and delivered by wholesalers and retail pharmacies that are **not** under contract with DOD (and that are not using a federally owned warehouse system). Thus, DOD's arrangement does not qualify as a depot under the first definition. Alternatively, a depot may include a system under which drugs are "procured by an agency" and delivered "directly from the commercial source to the **entity** using such covered drugs." *Id.* [Emphasis added.] Here, the drugs are not being delivered to an "entity." Instead, the drugs are being delivered to an individual, TRICARE beneficiary. In numerous Federal statutes, a distinction has been drawn between individuals and entities. *See, e.g.*, 5 U.S.C. § 601 (6); 42 U.S.C. § 3602 (n)(1); 49 U.S.C. § 70101 (1). Even the VA, in its public statements, has maintained this distinction. *See* 2000 WL 1073292 (F.D.C.H.), Testimony of Robert B. Betz, regarding proposed extension of FSS pricing to Federal Employees Health Benefits beneficiaries ("VA ...is

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negotiating on behalf of entities that serve our Nation's veterans"). For these additional reasons, the distribution system of the drugs does not qualify as a depot as that term is defined by the VHCA.

The Proposed Rule also asserts that the program is consistent with Congressional intent under 38 U.S.C. § 8126. GSA takes the position that DoD's TRICARE Retail Pharmacy Program is a centralized pharmaceutical commodity management system that meets the definition of "depot" contracting system as set forth in 38 U.S.C. § 8126. In fact, the legislative history contemporaneous to the statute reflects an understanding of "depot" radically different than the Proposed Rule contemplates. One of the relevant Senate Reports states:

> **Depot System:** "A second mechanism VA uses is its depot system, which accounts for approximately 25 percent of VA's total expenditures for drugs and biologicals. As part of this system, VA operates three large warehouses at which drugs and biologicals and other medical items are stored for distribution to VA health-care facilities. Depot prices for most drugs and biologicals historically have been even lower than FSS prices, because VA, rather than the manufacturer, bears the cost of distributing a drug or biological through the depot system." [Emphasis added.]

See Senate Report No. 102-401 ("Report"), at 62-63, *reprinted in* 1992 U.S.C.C.A.N. 4113, 4152-4153. Report No. 102-401 is a Committee Report addressing S. 2575, a Senate bill that was used in formulating the compromise legislation of H.R. 5193 (that became the VHCA). Thus, a fair reading of the legislative history is that it reflects a Congressional intent that discounted pricing should apply to depot sales where the Government bears the distribution costs. In that respect, the Proposed Rule is inconsistent with Congressional intent, since the Federal Agency Retail Pharmacy Program, including DoD's program, contemplates that the costs of the commercial distribution system are borne by each manufacturer.

In fact, the legislative history described in the Proposed Rule is that of a recent authorization act. The Senate Report cited, in recommending further decreases to program funding, noted that the program request did not reflect anticipated savings "when federal pricing authorized by the Secretary of Veterans Affairs under title 38, United States Code, is applied in a new retail pharmacy program." 70 Fed. Reg. at 19047. The assumption that program funding should be reduced to reflect anticipated savings cannot be bootstrapped into a reflection of Congressional approval for the VA's interpretation of the statute when there is no indication that the legality of the program was under consideration by Congress.

For these reasons, we submit that the proposed program is contrary to existing law and should not proceed.

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II. Conflicts With Federal Supply Schedule Contract Clauses

The proposed regulatory scheme also conflicts with clauses in the current VA Federal Supply Schedule contract that are prescribed by regulation for inclusion therein. For example:

- FAR 52.212-4(n) states that "title to items furnished under this contract shall pass to the Government upon acceptance. . . ." Thus, the contract contemplates that at some point, the Government would accept the drugs. Under the proposed procedures, the Government never accepts the drugs. Instead, it only reimburses a pharmacy for drugs after the drugs have been accepted by TRICARE beneficiaries.

- FAR 52.232-34, Payment by Electronic Funds Transfer Payment, provides, at paragraph (a)(1), "[a]ll payments by the Government under this contract shall be made by Electronic Funds Transfer. . . ." Because the Government is not paying the manufacturers under this contract for drugs purchased by TRICARE beneficiaries from retail pharmacies, arguably the contract is not intended to apply to such purchases.

- Paragraph AS1506, Chargeback Arrangements, states that chargeback arrangements must be coordinated between prime vendors and the Contractor and "[t]he Government will not become involved in this area. . . ."

- Paragraph AS3023, Diversion of Pharmaceutical Products, prohibits diversion. The clause, at paragraph (2), limits orders to those ordering activities listed on the appendices to GSA Adm. Order 4800.2E and pharmaceutical prime vendors ordering on behalf of an activity. If there appears to be a pattern of diversion, the contractor may elect to "accept only direct orders." Direct purchasing by TRICARE beneficiaries appears to conflict with the prohibition on diversion, as defined by the contract.

- Paragraph 552.211-78, Commercial Delivery Schedule, suggests that there are two types of orders under the contract: (1) orders placed directly with contractors, and (2) orders placed with a Government PPV. Since purchases

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by TRICARE beneficiaries do not fall into either category, they arguably are not covered by the contract.

- Paragraph G-FSS-914A, Contractor's Remittance, states that payment to the Contractor shall be paid by the Government by electronic funds transfer or check. The clause further provides that "[a]ll orders placed against a Federal Supply Schedule contract are to be paid by the individual agency placing the order." Here, because DOD will not make any payments to the Contractor for purchases made for TRICARE beneficiaries, such purchases do not appear to be contemplated by the contract.

- Paragraph 555.223-74, Invoice Payments, establishes when payments will be made to the Contractor for orders. This clause contemplates that the Government will make payments to the Contractor and will be liable for interest under the Prompt Payment Act when timely payments are not made. Again, the contract is intended to apply to orders made by agencies with payments by the agency to contractors. It is not intended to apply to purchases made by TRICARE beneficiaries.

In the event that the program were ultimately deemed to be in compliance with existing law, it still would be necessary for GSA to make appropriate revisions to these contract clauses.

III. Implementation Issues

In addition, there are a number of questions and issues relating to implementation of specific regulatory provisions in the Proposed Rule. We have identified several of these below.

48 CFR 552.238-XX (g)(3), Contractor Refund and Reporting Schedule, subsection (2), requires that the Contractor send a "Reconciliation Report." We request that GSA prescribe the format required for the Reconciliation Report, and detail the contents thereof.

48 CFR 552.238-XX (i), Industrial Funding Fee and Sales Reporting, indicates that "sales are counted as FSS sales on the date the computations are finished (for example, the results of computations finished on March 10 are reported 60 days after the end of the first calendar quarter, on May 30)." We interpret this to mean that the "appropriate FSS contract prices" are those in effect

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on the date the manufacturer completes its refund calculations, not the date the drug is dispensed or the date of issuance of the Utilization Flat File Layout Report. This may result in significant distortions in the calculations if the FSS prices change during the reporting period, given that there will be a significant time lag between the manufacturer's date of sale and the date the refunds are calculated.

Implementation of the sales reporting as proposed could create numerous implementation issues regarding calculation of Average Manufacturer Price ("AMP") and Best Price ("BP") under the Medicaid Drug Rebate Program. FSS sales are excluded from the calculation of AMP and Best Price under that program. The DoD-supplied FSS retail sales data, which reflects the date the product was dispensed to the TRICARE beneficiary, will not match the manufacturer's date of sale (*i.e.*, the date the manufacturer sold the drug to its wholesaler) for purposes of identifying the FSS retail sales and units to be removed from AMP. This will result in a significant administrative burden for manufacturers to match the data retrospectively and submit AMP restatements at a later date.

We respectfully request that GSA consider minimizing the disparate approaches between the Federal Agency Retail Pharmacy Program and the Medicaid Drug Rebate Program and the attendant implementation issues the Proposed Rule will create and that GSA coordinate resolution of such issues with the Centers for Medicare and Medicaid Services.

***

Again, Epstein Becker & Green, P.C. appreciates this opportunity to comment on the Proposed Rule on behalf of certain of our clients and we look forward to further discussion of these issues. In the interim, please contact us if you have any questions or require further information relating to these comments.

Sincerely,

Constance A. Wilkinson

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June 13, 2005

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Via E-mail and Fax
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Re: GSAR Case 2005-G501

Dear Ms. Duarte:

I am writing on behalf of Mallinckrodt Pharmaceuticals in order to comment on the above referenced proposed rule published in the April 12, 2005, issue of the *Federal Register*. Mallinckrodt Pharmaceuticals believes that not only is it a privilege to participate in this process, but that it is part of the organization's civic duty to provide relevant comments to the agency on issues raised by this proposed rule.

It is obvious to all, including Mallinckrodt Pharmaceuticals, that the TriCare program would benefit greatly from a reduction in its health care costs, including pharmaceuticals, and that this would benefit the entire United States. These benefits, however, are not sufficient to justify and authorize the proposed rule. Accordingly, Mallinckrodt Pharmaceuticals feels compelled to comment on how the authority for the proposed rule cited in the preamble fails to authorize the program regardless of the worthiness of its goals and that the proposed rule will often result in an ultimate price to TriCare that exceeds the maximum allowed under the statute.

The proposed rule relies on the Veteran's Health Care Act of 1992, *codified at* 38 U.S.C. §8126, ("VHCA") as its primary authority for including TriCare retail pharmacy purchases within the scope of federal procurement regulations to which a manufacturer must comply. This reliance, however, is misplaced because these purchases are not federal procurements from the manufacturer. Whatever TriCare pays for a drug at the retail level has nothing to do with the manufacturer as TriCare's payment rate is negotiated between Express Scripts, as TriCare's fiscal intermediary, and the retail pharmacy. The manufacturer takes no part in those negotiations and has no control over them, yet the proposed rule purports to require the manufacturer to pay a refund because of some perceived overpayment to the manufacturer in this transaction.

Furthermore, the concept of a "virtual depot" upon which the proposed rule's reliance on the VHCA for authority is premised is also flawed. The VHCA defines a "depot" as a:

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> Centralized commodity management system through which covered drugs procured by an agency are –
>
> (A) received, stored, and delivered through –
>
> (i) a federally owned and operated warehouse system, or
>
> (ii) a commercial entity operating under contract with such an agency; or
>
> (B) delivered directly from the commercial source to the entity using such covered drugs.

38 U.S.C. §8126(h)(3). TriCare's arrangements, however fail to meet this definition. First, the agency never receives the goods in a warehouse at any time while the retail pharmacies that store and deliver the product to beneficiaries have no contract with TriCare or its constituent agency but only with Express Scripts. In addition, drugs purchased by TriCare at the retail level and dispensed to beneficiaries are not delivered to a federal entity, but instead are delivered directly from the pharmacy to a private individual. Since the "virtual" program set up by TriCare fails to meet any of the definitional elements under the VHCA for a depot program, it is not a depot under that statute and any reliance on the VHCA for authority is misplaced.

As further evidence of this, the refund process outlined in the proposed rule fails to guarantee that TriCare receives the ultimate price that if feels it is entitled to under the VHCA. In all instances, TriCare's true net price will be the contract price it pays to the retail outlet that is dispensing the drug minus the manufacturer's refund. Presumably in most, if not all, instances the payment accepted by the retail pharmacy will be more than it paid for the drug. The refund that a manufacturer will pay under the proposed rule, however, is the difference between either Nfamp or actual contract price, if it can be identified, and the FSS price. For those situations in which TriCare's refund was based on Nfamp rather than contract price, even after you reduce the price paid by TriCare by any refund received, TriCare's retail cost will be more than Nfamp, so its net price will exceed the FSS price. In other words, TriCare will still have been "overcharged" under the requirements of the VHCA even though it is paying an agreed upon rate at the retail level.

This is because of the lack of privity between the manufacturer and the retail purchase by TriCare – something not anticipated by the VHCA. The VHCA clearly anticipates that an agency utilizing its prices is purchasing either directly from the manufacturer, or from its agent, a wholesaler, who has agreed to be bound by the manufacturer's FSS price. The retailer, however, is compelled by business reasons to charge a higher price than the manufacturer's FSS price, so that the agency is ultimately paying more than it is required to under the VHCA.

In addition, the proposed rule also relies on Public Law 105-261, the National Defense Authorization Act of FY 1999, as authority for the proposed rule through that statute's mandating of improved benefits for the TriCare program as a military morale issue. The proposed rule, at 70 Fed. Reg. 19047 (April 12, 2005), cites Section 703 of Public Law 105-261 as directing the redesign of the TriCare program "by incorporating 'best business practices' and of the private sector." Yet the "best business practices of the private sector" that the proposed rule is attempting to implement are the low, government-only prices of the Federal Supply Schedule ("FSS") that are mandated by the VHCA and not accessed by any private sector businesses. It seems that instead of

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providing statutory authority for the proposed rule, the cited section of Public Law 105-261 actually suggests that TriCare should be looking somewhere other than the VHCA as the basis for its redesign of its benefits.

The points outlined above are being raised to show that the proposed rule, while worthy in its objectives, is not authorized by the statutes it purports to authorize it, nor does it guarantee that the resulting transactions will comply with the statutory scheme. Rather than attempt to try to stretch existing regulatory authority to meet that worthy goal, it seems that a more workable solution is for TriCare to approach individual manufacturers about voluntary rebates or refunds. This strategy comports with the mission to use "commercial best practices" as it is the normal methodology for pharmacy benefit managers, like Express Scripts, to try to manage costs and deliver pharmacy services at as reasonable a cost as possible. Mallinckrodt Pharmaceuticals would welcome such discussions.

Sincerely,

Brian Elsbernd

Brian Elsbernd
Government Contracting and Compliance Manager
Mallinckrodt Pharmaceuticals

2005 G501-6

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June 13, 2005

By Facsimile and Hard Copy to Follow

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ATTN: Ms. Laurieann Duarte

RE: GSAR case 2005-G501: Federal Agency Retail Pharmacy Program

Dear Ms. Duarte:

GlaxoSmithKline (GSK), a leading research-based pharmaceutical company, appreciates the opportunity to respond to the U.S. General Services Administration's (GSA's) request for comments on its April 12, 2005 Proposed Rule, entitled "Federal Agency Retail Pharmacy Program Supply Schedule." Given that GSK makes its products available to the government under Federal Supply Schedule (FSS) contracts, we would be substantially impacted by this Proposed Rule.

As a preliminary point, GSK recognizes that the Proposed Rule, if implemented, would result in cost savings for the VA and DoD, both of which are tasked with providing health care to growing populations while confronting shrinking pharmaceuticals budgets. GSK is particularly sensitive to the formidable constraints that are being imposed on these agencies' pharmaceuticals budgets. However, we at GSK believe that the only appropriate and truly effective method to achieve continued savings on prescription drugs will involve a commercial market-based solution.

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A. Overview of the Proposed Rule

The Proposed Rule would amend the GSA Regulations (GSAR) to require the incorporation of a new contract clause in pharmaceutical FSS contracts under which contractors would have to pay "refunds" based on retail pharmacy utilization under Federal Agency Retail Pharmacy Programs that the Department of Veterans Affairs (VA) has determined qualify as "depots" under the Veterans Health Care Act of 1992 (VHCA). 70 Fed. Reg. 19045. The first such program would be the TRICARE Retail Pharmacy Program (TRRx) of the Department of Defense (DoD). However, other similar PBM-administered retail reimbursement programs of the VA, and, potentially, the Public Health Service, also would be eligible for such refunds if any such programs were held to meet the VHCA definition of depot.

Under the proposed clause, prescription units of covered drugs ordered through a Federal Agency Retail Pharmacy Program would be "deemed" to be ordered under FSS contracts. The rule would consider the FSS orders to occur when a PBM network pharmacy dispenses drugs to a beneficiary of a Federal program. The manufacturer would be required to refund to the Federal agency the difference between a "benchmark" commercial price and the FSS contract price (FCP or the negotiated FSS price for the drug, whichever is lower). Importantly, however, the refund payment would not constitute a refund of the difference between the FSS contract price and the price the Federal agency actually paid to reimburse the retail pharmacy for the drugs dispensed to the Federal beneficiary. This is because the price paid by the Federal agency to reimburse the retail pharmacy has no relationship to the commercial price benchmark used to compute the required refunds.

Additionally, given that PBM network retail pharmacy utilization would be considered to give rise to deemed FSS contract orders, manufacturers would be required under the proposed clause to include these pharmacy prescriptions as FSS sales in their quarterly FSS sales reports and to pay the Industrial Funding Fee ("IFF") on those sales.

B. The Proposed Rule Is Not Authorized by Law

GSK supports GSA's continued efforts to streamline the FSS contracting system and bring private sector efficiencies to government procurement within the legal confines of Federal procurement law. The Proposed Rule, however, does not accomplish this goal as GSA does not have the requisite statutory authority to apply VHCA-based price ceilings to Federal agency retail pharmacy reimbursement programs.

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As discussed in detail in the comments prepared by the Pharmaceutical Research and Manufacturers of America (PhRMA), although various statutes are referenced in the preamble to the Proposed Rule as providing authority for the instant rulemaking, none of the cited authorities provides GSA with the authority to impose a retail refund requirement under the FSS contracts. *This is because the refunds contemplated are not provided in connection with drug procurements by the Federal government.* Given that the Proposed Rule is envisioned to apply widely to all Federal Agency Retail Pharmacy Programs – starting with TRRx, but, potentially expanding beyond to other VA and PHS agency refund programs, including, for example, the VA Community-based Outpatient Clinics, it is essential that the rule be grounded in a sound legal structure. Accordingly, we respectfully request that GSA suspend the Proposed Rule.

C. Implementation Considerations

If GSA were to proceed with the Proposed Rule despite the serious legal considerations noted above (and discussed more thoroughly by PhRMA in its comments), there are a number of aspects of the rule that would require clarification to ensure consistent and fair operation of Federal Agency Retail Pharmacy Programs under FSS contracts. A number of these required clarifications are set forth below.

1. Application of Proposed FSS Clause to FSS Contracts

The proposed FSS provision set forth at 538.XX02, entitled "Contract Clause," within the Proposed Rule provides that "the contracting officer shall insert the [new FSS] clause ... in solicitation and schedule contracts for Schedule 65, Part I ."[1] This text can be read to imply that the VA would be authorized to revise existing FSS contracts to incorporate the proposed FSS clause. While the VA likely could insert a new clause in future FSS solicitations (to the extent such clause were authorized by statute), the Proposed Rule does not make clear how the VA could incorporate the clause into an existing FSS contract unilaterally. Under FAR 52.212-4(c), which is incorporated into the standard language of FSS contracts for pharmaceuticals, a bilateral written agreement is required to effectuate a change to the basic terms and conditions of the contract.[2]

In view of this established legal requirement, if the government sought to unilaterally amend existing FSS contracts to incorporate the Federal Agency Retail Pharmacy Program clause without negotiating with the contractor and

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1 *See* 70 Fed. Reg. at 19050.

2 A tailored version of FAR 52.212-4(c) appears in pharmaceutical FSS contracts, and provides that "[c]hanges in the terms and conditions of this contract may by made only by written agreement of the parties."

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providing consideration for the modification, that action would constitute a breach of contract.[3] We therefore request that clarification be provided to pharmaceutical manufacturers regarding how the government intends to implement the proposed clause. We suggest that GSA modify the Proposed Rule to specify that the proposed FSS clause implementing the refund requirement would not be imposed on existing contracts, but, if the rule is promulgated, would only be inserted into the FSS contract solicitation for application to contracts awarded thereafter.

2. Benchmark Price for Refund Calculation

The Proposed Rule requires "refunds" paid by manufacturers to be "based on the difference between a benchmark price, consisting of either the manufacturer's actual sales price to the wholesaler or retail pharmacy chain when known and auditable or non-FAMP (non-Federal Average Manufacturer Price), and the Federal Supply Schedule price...."[4] This language does not make clear that under the proposed clause the manufacturer would have the discretion to utilize either an actual sales price or the Non-FAMP as its calculation benchmark for purposes of determining the refunds due to the government.

The requirement to use either commercial pharmacy pricing or Non-FAMP as the benchmark from which to calculate the applicable Federal refund is patterned on the refund calculation benchmark requirements put forth by DoD in the context of its TRRx Program.[5] Moreover, DoD has indicated that manufacturers may – at their discretion – choose to apply Non-FAMP as the benchmark in the refund calculation for certain products, while using the direct contract price as the benchmark for other products. Given that the TRRx Program leaves the decision as to which price to use as a benchmark for the refund calculation up to the manufacturer, we would suggest that the proposed FSS clause be clarified to be consistent with this approach. In addition, we would suggest that the text of the Proposed Rule be revised to specify that the manufacturer would be free to choose the appropriate benchmark for each NDC and that it could make the determination as to which benchmark to use on a quarterly basis.

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3 *See, e.g., United States v. Winstar Corp.*, 518 U.S. 839 (1996) (Justice Souter's plurality opinion); *SMS Data Prods. Group, Inc. v. United States*, 17 Cl.Ct. 1, 9 (1989) (government cannot unilaterally change one of its contracts without being held liable in damages for breach of contract); *see also* FAR 52.212-4(c).

4 70 Fed. Reg. at 19050.

5 *See* TRRx Process and Procedures Guide at 11 ("At the discretion of the manufacturer, the basis on which refunds will be calculated will be either Non-FAMP or direct contract sales.")

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3. Payment of the Industrial Funding Fee (IFF)

a) IFF Should Not Be Assessed on "Deemed Orders" Under Federal Agency Retail Pharmacy Programs

Subsection 552.238-XX(i) of the proposed FSS clause would require FSS contractors to remit the Industrial Funding Fee (IFF) based on deemed orders under Federal Agency Retail Pharmacy Programs. However, in our view, requiring contractors to pay the IFF based on purchases by retail pharmacies – purchases that are commercial in nature and to which the government is not a party – is inappropriate.

FSS contract clause 552.238-74 ("Industrial Funding Fees and Sales Reporting (JUL 2003) (VARIATION)") provides that the IFF is to be paid based on sales transacted under the FSS contract. Accordingly, under this IFF and Sales Reporting Clause, contractors are permitted to establish sales tracking and reporting systems keyed to various points of sale, including 1) order receipt date; 2) shipment date; 3) invoice date; and 4) payment date. As is evident, the IFF payments are based on FSS contract sales. However, under the Federal Agency Retail Pharmacy Programs, there are no actual FSS contract orders. Rather, product purchased through commercial channels is deemed to be ordered under the FSS when dispensed to a Federal beneficiary. There is no FSS task or delivery order, and no dollar value to report for the FSS sale, because there would be no order made under the FSS contract. Accordingly, given that there is no actual FSS order or sale when prescriptions are dispensed to Federal beneficiaries through retail pharmacies, we do not see the legal basis for requiring the payment of the IFF on these transactions.

More fundamentally, as is clear from the IFF and Sales Reporting Clause, the IFF is a fee that is intended to fund VA's administration of the FSS contracting program. However, the VA does not have any role (administrative or otherwise) in the deemed orders contemplated under the Proposed Rule. Again, these transactions involve purchases by retail pharmacies that are purely commercial in nature – i.e., they are transacted through commercial channels, pursuant to commercial agreements (if any), and transacted through commercial wholesaler arrangements. There simply is no nexus between the FSS contract and these deemed orders. Accordingly, there is no basis for the IFF payment based on these transactions.

In view of the above, we suggest that GSA delete subsection (i) of the proposed FSS clause.

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b) Refund Reference Point Requires Clarification

To the extent that the IFF requirement were not deleted from the proposed FSS clause, at a minimum it would be necessary to clarify the FSS price to be used in determining the refunds due based on deemed orders under Federal Agency Retail Pharmacy Programs. This would be necessary to accommodate the different approaches that manufacturers are permitted to take with respect to how they account for the IFF.

As indicated above, the IFF is an administrative fee that FSS contractors must pay to the VA to cover the costs of administration of the FSS contracting system. Currently, the IFF for FSS pharmaceuticals contracts is 0.5% of the FSS price. Manufacturers have the option either to "embed" the IFF in their FSS prices (i.e., to add the fee to the basic FSS price, so that the government purchaser effectively covers the fee) or to "absorb" the IFF (i.e., to pay the IFF out of pocket).

GSK has opted to embed the IFF in its FSS contract pricing. The hypothetical below demonstrates generally how the FSS prices are increased to include the 0.5% IFF.[6]

FSS Price without IFF = $150.00
FSS Price with IFF = ($150 * 1.005) = $150.75

To identify and extract the IFF amount from total FSS contracts sales, the following calculation is performed:

(Total FSS Sales * 0.995) * 0.005 = IFF

Under the Proposed Rule, the IFF would be calculated based on "sales" of FSS NDC-11 package units (rounded down from prescription units). The contractor would then have to remit this IFF amount to the VA. However, following the approach discussed in the Proposed Rule would result in a situation where a company that has opted to embed the IFF has to pay the IFF out of pocket – just as if it had agreed to absorb the IFF as did Company B. The following hypothetical demonstrates this point:

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[6] The FSS Price with IFF is calculated to three decimals and rounded to two decimals.

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GlaxoSmithKline

FSS IFF Calculation	Company A *Embedded*	Company B *Absorbed*
NDC-11 FSS Base Price	$150	$150
IFF (.5%) Per Unit	$.75	$.75
FSS Price w/IFF	$150.75	N/A
Total Number of NDC-11 Units[7] "Ordered" During Quarter under Federal Agency Retail Pharmacy Program	1000	1000
*IFF Due Under Proposed Rule (FSS w/IFF[8] * Units * .5%)*	(($150.75 * 1000) * 0.995) * 0.005 = $750	(($150.75 * 1000) * 0.995) * 0.005 = $750

To ensure that Company A, which chooses to embed the IFF, is not required to pay the IFF out of pocket (which it is not required to do under the agreed terms of its FSS contract), the Proposed Rule should be clarified to require the Federal agency in charge of the Federal Agency Retail Pharmacy Program to cover the IFF. Given that the FSS "sales" under Federal Agency Retail Pharmacy Programs are rebate-based, it will be necessary to reduce the amount of the agency rebate paid in order for the agency to cover the IFF. This can be effected by permitting companies that embed the IFF to use the FSS price with IFF as the benchmark FSS price for purposes of the rebate calculation. The following hypothetical demonstrates this point:

Rebate Calculation	Company A *Embedded*	Company B *Absorbed*
FSS Base Price	$150	$150
FSS Price w/IFF	$150.75	N/A
Applicable Non-FAMP	$190	$190
Total Number of NDC-11 Units[9] "Ordered" During Quarter	1000	1000
*Refund = (Non-FAMP[10] – FSS Price) * Units*	Use FSS w/IFF ($190 – $150.75) * 1000 = $39,250	Use FSS w/o IFF = ($190 – $150) * 1000 =$40,000

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7 This includes all prescription units dispensed through a Federal Agency Retail Pharmacy Program. The figure is rounded down to the nearest full package size.

8 Note that under the proposed FSS clause, the IFF calculation based on Federal "sales" is required to be performed based on the FSS price *including the* IFF. It appears to require that this approach be taken across-the-board, without regard to whether a company embeds or absorbs the IFF.

9 This includes all prescription units dispensed through Federal Agency Retail Pharmacy Program. The figure is rounded down to the nearest full package size.

10 Note that the example assumes that the benchmark commercial price for purposes of the refund calculation is the Non-FAMP and not a retail pharmacy contract price.

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As can be seen, allowing a company that embeds the IFF to use the FSS with IFF as the "FSS price" in the rebate calculation would allow its rebates to be adjusted downward so that the Federal Agency Retail Pharmacy Program would pay the IFF – and not the company. We therefore suggest that the proposed FSS clause be clarified to specify that FSS with IFF be used as the FSS price benchmark in the rebate calculation.

D. "Covered Drugs" Under the Proposed Rule

The proposed FSS clause in the Proposed Rule does not adequately define the term "covered drugs." The Introduction and Background sections of the Proposed Rule make clear that the rule is intended to extend "Federal pricing" – determined pursuant to the terms of the VHCA – to Federal Agency Retail Pharmacy Programs of the VHCA Big 4 Federal agencies.[11] The VHCA establishes price ceilings only for "covered drugs," which it defines as innovator drugs (both single and multiple source), biologics, and certain insulin products.[12] It is therefore clear that the intent of the Proposed Rule is to require refunds only for VHCA "covered drugs." However, the text of the proposed FSS contract clause does not provide a definition for the term "covered drugs." Accordingly, we suggest that the Proposed Rule be clarified to define the term "covered drugs" and to indicate that refund payments would only be required based on retail utilization of VHCA "covered drugs."

IV. Conclusion

Based on the foregoing, GSK believes that GSA lacks authority to proceed with the Proposed Rule. However, to the extent that GSA were to finalize the Proposed Rule, GSK would urge the government to closely consider and resolve the implementation issues described in our Comments.

Please note that this letter contains confidential and proprietary business information. We therefore request that this document be protected from disclosure under the Freedom of Information Act (5 U.S.C. §552, as amended).

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11 The Big 4 agencies include VA, DoD, the Public Health Service and the Coast Guard.
12 8 U.S.C. § 8126(h)(2).

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GSK appreciates the opportunity to comment on the Proposed Rule and is available to provide any additional information or assistance.

Sincerely,

Dale Nimmo

Dale E. Nimmo
Assistant General Counsel

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PhRMA

June 13, 2005

BY HAND DELIVERY

Ms. Laurieann Duarte
General Services Administration
Regulatory Secretariat (VIR)
1800 F Street, N.W., Room 4035
Washington, D.C. 20405

Re: GSAR Case No. 2005-G501

Dear Ms. Duarte:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to comment on the Proposed Rule published by the General Services Administration ("GSA") on April 12, 2005.[1] PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA recognizes the extraordinary sacrifices made by the men and women of our military and is committed to doing its part to assure that they have access to the best possible medicines and the highest quality health care. We offer these comments because we do not believe the Proposed Rule is the best way to achieve our mutual objective of making available the best quality care to our military personnel and their dependents. Additionally, we believe that the underpinnings of the Proposed Rule are not sound.

The Proposed Rule would establish a supplemental General Services Administration Regulation ("GSAR") clause, entitled "Federal Agency Retail Pharmacy Program Supply Schedule," that could be incorporated into the Federal Supply Classification ("FSC") Group 65 Federal Supply Schedule ("FSS") contracts. This new clause would permit the Department of Defense ("DoD"), the Department of Veterans Affairs ("VA"), the Coast Guard, and the Public Health Service ("PHS") (collectively, "the Big Four") to obtain rebates, referred to in the Proposed Rule as "refunds," from FSS contractors on sales of "covered drugs" dispensed through a qualifying "Federal Agency Retail Pharmacy Program." The clause also would require FSS contract holders to report qualifying retail pharmacy sales to the VA and allow the VA to collect an Industrial Funding Fee ("IFF") on those sales. The clause would not affect the amount

[1] 70 Fed. Reg. 19,045 (Apr. 12, 2005).

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that beneficiaries of the TRICARE health system (or any other health system) would pay for their prescriptions.[2] Nor would it increase, improve, or affect beneficiary access to medicines.

The Proposed Rule should be withdrawn for two general reasons:

(1) The GSA lacks statutory authority to implement the Proposed Rule; and

(2) The Proposed Rule would create significant operational problems for both the VA and FSS contract holders.

The most effective means to meet the budget objectives cited as the basis for the Proposed Rule is the competitive marketplace, not the extension of price controls or other artificial price constraints or price ceilings as the Proposed Rule contemplates.[3] The commercial sector employs several types of market-based approaches, including competitive negotiations.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), passed by Congress and signed into law by President Bush on December 8, 2003, establishes a market-based approach for managing the new prescription drug benefit for the more than 40 million Americans who are enrolled in the Medicare program.[4] In our view, a similar market-based solution would work well for the DoD and the VA in their efforts to develop a retail pharmacy benefit, where the government's role is as a third-party payer as opposed to a direct provider of the prescription drugs that are dispensed to its beneficiaries. And, unlike with the approach set forth in the Proposed

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[2] The cost shares paid by TRICARE beneficiaries are defined in a Uniform Formulary Rule issued on April 1, 2004. *See* 69 Fed. Reg. 17,035 (Apr. 1, 2004).

[3] Indeed, prior government reports have suggested that making FSS pricing available to the private sector would have unintended adverse consequences for the prices for other health benefit plans. *See, e.g.*, Gen. Accounting Off., Pub. No. GAO/HEHS-00-118, Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes (Aug. 7, 2000).

[4] Among other provisions, the MMA requires that there must be at least two approved prescription drug plans per Medicare region from which beneficiaries may choose and that each drug formulary must contain at least two drugs per therapeutic class. MMA, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

Rule, we are not aware of any statutory or regulatory impediments to the development of market-based approaches to cost containment by either the DoD or the VA.[5]

For the reasons stated in this letter, the GSA should withdraw the Proposed Rule and encourage the DoD, the VA, and other Federal agencies to pursue market-based solutions as alternatives to the "refund" process that the Proposed Rule contemplates.

I. The Proposed Rule Is Not Authorized by Law

A. The GSA is Not Authorized to Promulgate the Proposed Rule

The principal defect with the Proposed Rule is that it is outside of the GSA's statutory authority. Accordingly, we believe that the GSA's promulgation of the rule would be an ultra vires agency action. It also would be fundamentally at odds with one of the five major objectives of the GSA's "Get it Right" plan to: "ensure compliance with federal acquisition policies, regulations and procedures."[6]

The preamble to the Proposed Rule does not specify the statute or statutes under which the rule would be issued or explain how the Proposed Rule itself would be consistent with Congressional intent. However, the preamble and the rule reference three statutes that the GSA apparently believes support parts or all of the Proposed Rule: (1) Section 603 of the Veterans Health Care Act of 1992 ("VHCA"), 38 U.S.C. § 8126; (2) Sections 201(a) and 309 of the Federal Property and Administrative Services Act ("FPASA"), 40 U.S.C. § 501 and 41 U.S.C. § 259(b); and (3) the National Defense Authorization Acts of 1999 and 2000, 10 U.S.C. § 1074g. None of these statutes contemplates the rule under consideration.

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[5] As explained in section I.A.3 below, use of a market-based solution would be consistent with the Congressional requirement that DoD adopt "the best business practices of the private sector" in establishing an integrated and uniform health benefit for its beneficiaries. *See* 10 U.S.C. § 1074g(a) (2004).

[6] *See* Gen. Servs. Admin., Get It Right: A Comprehensive, Governmentwide Approach at 7, *available at* http://www.gsa.gov/gsa/cm_attachments/GSA_DOCUMENT/GIRight%20_org_pre-R2_iP1B_0Z5RDZ-i34K-pR.ppt/269.

1. The Veterans Health Care Act of 1992, 38 U.S.C. § 8126

Summary of the VHCA. In relevant part, the VHCA requires manufacturers of "covered drugs" to enter into Master Agreements and Pharmaceutical Pricing Agreements ("PPAs")[7] with the VA under which manufacturers agree to make a statutorily-mandated discount, known as the Federal Ceiling Price ("FCP"), available to the Big Four agencies for all of the manufacturer's covered drugs that are "purchased under depot contracting systems or listed on the Federal Supply Schedule."[8] The VHCA defines the term "depot" as:

> a centralized commodity management system through which covered drugs procured by an agency of the Federal Government are –
>
> (A) received, stored, and delivered through –
>
> (i) a federally owned and operated warehouse system, or
>
> (ii) a commercial entity operating under contract with such agency; or
>
> (B) delivered directly from the commercial source to the entity using such covered drugs.[9]

The Proposed Rule concludes that a Federal Agency Retail Pharmacy Program would qualify for Federal pricing because it would constitute a "virtual" depot contracting system, but does not articulate the statutory basis for this conclusion.[10] Indeed, as described below, this conclusion lacks statutory support.

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[7] If a manufacturer does not have an executed Master Agreement and PPA, then it may not receive payment for purchases under Medicaid and other programs. *See* 38 U.S.C. § 8126(a)(4).

[8] *Id.* § 8126(a)(2).

[9] *Id.* § 8126(h)(3).

[10] 70 Fed. Reg. at 19,050 (Subsection (c)(2) of the proposed clause notes that a Federal Agency Retail Pharmacy Program is a "virtual depot system").

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The VHCA Is Narrow in Scope. Congress intended for the VHCA to have a limited application. Both the Senate and the House Committee Reports relating to the VHCA recognized the four means by which the VA and DoD procured drugs (FSS contracts, a depot system, a single award contract and open market purchases)[11] and extended the FCP to procurements made through only the first two of those methods. Congress did not reference DoD reimbursement for drugs dispensed under the CHAMPUS program (the TRICARE predecessor civilian health insurance program), thus demonstrating Congress' intent that the FCP should not apply to government reimbursement programs, such as a retail pharmacy program.[12]

The VA has previously construed the VHCA consistent with Congress' intent. Until recently, the VA defined the term "depot" to include only "centralized commodity management systems through which covered drugs are: (A) received, stored and delivered to a listed federal agency through a federally-owned warehouse system or a commercial warehouse system operating under contract with the procuring federal agency; or (B) delivered directly from the manufacturer or its agent to a listed federal agency's ordering activity at its purchasing address."[13] Neither of the definitions that the VA previously used would encompass a Federal Agency Retail Pharmacy Program where there is no procurement contract between the drug manufacturer and the government or the government's purchasing agent. Furthermore, the VA expressly concluded in 1994 that the VHCA "does not require manufacturers to grant the discount to . . . government contractors authorized to use the FSS" and specifically characterized the VHCA as imposing a "limited" discount.[14] These statements are directly at odds with the

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[11] S. Rep. No. 102-401, at 62-63 (1992); H.R. Rep. No. 102-384 (I), at 4 (1991).

[12] In promulgating the VHCA, Congress understood the important distinction between the government as a third party payer and the government as a direct purchaser of drugs, and understood that the latter could result in a depot contracting system whereas the former could not. *See* S. Rep. 102-228(I), DEVELOPMENTS IN AGING: 1990-VOLUME 1, 1991 WL 52579 at *254 (Mar. 22, 1991) (recognizing that depot prices are excluded from best price calculation under the Medicaid Rebate statute because "depot prices reflect the manufacturer's costs of delivering the product in bulk to a provider, without packaging costs" and that, because "Medicaid is a reimbursement system, not a direct purchaser of drugs," it would be "unfair for Medicaid to have access to prices that are determined based on this mode of distribution.").

[13] Letter from Phillipa L. Anderson, Assistant General Counsel, Dep't of Veterans Affairs, to Robert D. Seaman, General Counsel of TRICARE Management Activity (Nov. 1, 2001). (Attached as Exhibit A).

[14] Letter from William E. Thomas, Jr., Assistant General Counsel, Dep't of Veterans Affairs, to Lt. Col. Henry L. Smith, OASD (HA) HSF/MCO, the Pentagon 1 (July 28, 1994). (Attached as Exhibit B).

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unprecedented interpretation of "depot" that underlies the Proposed Rule's conclusion that a retail pharmacy program qualifies as a depot contracting system.[15]

The DoD has also previously recognized that the VHCA does not authorize agencies to apply the FCP to retail pharmacy sales. Following a 1996 VA letter to covered drug manufacturers rejecting a DoD request to apply the VHCA to TRICARE network retail pharmacies, the DoD expressly sought legislation "to specifically bring the procurement of pharmaceuticals on behalf of DoD by an authorized contractor through an authorized retail pharmacy or mail order program within the purview of 38 U.S.C. § 8126."[16] Congress did not change the law in response to the DoD's request. The DoD's decision to seek such legislation confirms the DoD's understanding that the VHCA did not then, and therefore does not now, extend to retail pharmacy sales.[17]

The Proposed Rule Conflicts with the VHCA Definition of "Depot."
Notwithstanding Congress' intent that the VHCA apply only to Federal procurements of covered drugs and the VA and DoD's prior interpretation of the VHCA, the preamble to the Proposed Rule concludes that: "[t]his rulemaking is consistent with the authority provided by 38 U.S.C. § 8126 to acquire drugs at the statutorily provided discount through use of a depot contracting system."[18] PhRMA respectfully disagrees. As the VA previously concluded, the term "depot" in the VHCA does not extend to retail pharmacy programs and does not apply to "virtual" depot contracting systems. The definition of "depot" in the VHCA specifically requires a "centralized commodity management system" through which covered drugs are "procured" by an agency of the Federal government. The term "procurement" has a well-established meaning: it refers to the

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[15] In October 2004, the VA announced to covered drug manufacturers that DoD's TRICARE Retail Pharmacy ("TRRx") Program complied with the VHCA because the retail pharmacy benefit as structured was a "virtual" depot contracting system. Letter from Steven Thomas, Acting Executive Director, VA National Acquisition Center, to Manufacturer of Covered Drugs (Oct. 14, 2004). (Attached as Exhibit C). However, the VA did not explain the basis for this conclusion or explain why its interpretation of the VHCA changed.

[16] White Paper for the Office of the Secretary: TRICARE and Federal Ceiling Prices at 4 (Oct. 10, 2002). (Attached as Exhibit D).

[17] *Id.*

[18] 70 Fed. Reg. at 19,046.

acquisition of goods and services with appropriated funds for the government's benefit or use.[19]

The drugs that would be dispensed through a Federal Agency Retail Pharmacy Program are not "procured" by a Federal agency. Instead, the retail pharmacy would procure the drugs through its contracts with commercial wholesalers or manufacturers, and the program beneficiary in turn would procure the drugs from the retail pharmacy. The Federal government would never take title to or possession of the drugs. There would be no procurement contract under which drug manufacturers agree to provide the covered drugs in question to the Federal government or a vendor or agent of the Federal government.[20] Nor would there be any contract under which manufacturers agree to make the FSS (or FCP) available for the drugs that are dispensed through retail pharmacy programs. The government's sole role in the retail pharmacy transaction would be to authorize the pharmacy to fill the prescription and to reimburse the pharmacy (after the fact) for the government's share of the retail price.[21] Because there would be no Federal procurement of the drugs that are involved in this transaction, a Federal Agency Retail Pharmacy Program would not qualify as a depot contracting system under the VHCA.

The Proposed Rule Does Not Explain Why a Federal Agency Retail Pharmacy Program Would Qualify as a Depot Contracting System. As noted, contrary to prior determinations, the Proposed Rule concludes without explanation that the Federal Agency Retail Pharmacy Program procedures established in the proposed clause "are consistent with 38 U.S.C. § 8126."[22] The GSA must specify the basis for this

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[19] *See* 41 U.S.C. § 403 (2003); 48 C.F.R. § 2.101 (2005). *See also Appeal of Mayer*, HUDBCA No. 83-823-C20, 84-2 BCA ¶ 17,494 (1984) ("acquisition by purchase, lease, or barter, of property [or] services *for the direct benefit or use* of the Federal Government ... characterizes a Federal procurement.") (emphasis added).

[20] Retail pharmacies are not prime vendors or purchasing agents of the Federal government.

[21] Both the Federal Acquisition Regulations ("FAR") and the VA rules include insurance transactions and subsidies, such as a Federal Agency Retail Pharmacy Program, within the definition of "nonprocurement transactions." FAR § 9.403 (2005); 38 C.F.R. § 44.970 (2005).

[22] 70 Fed. Reg. at 19,050.

conclusion.[23] In particular, the GSA does not specify the part of the VHCA definition of "depot" that authorizes a Federal Agency Retail Pharmacy Program. If the GSA believes that the second alternative definition of depot (*i.e.*, direct delivery of the covered drugs from a commercial source to the entity using the covered drugs) supports this conclusion, then, at a minimum, the GSA must identify the entities that it believes constitute the commercial source and the end user of the covered drugs that would pass through the Federal Agency Retail Pharmacy Program.

Likewise, the Proposed Rule does not specify the contractual basis for its apparent conclusion that a Federal Agency Retail Pharmacy Program involves a Federal procurement. For example, the Proposed Rule does not identify any procurement contract under which a manufacturer agrees to sell the covered drugs that would be dispensed through the retail pharmacy program to a Federal agency or an authorized purchasing agent for the Federal price. Nor does the Proposed Rule identify a contract between a Federal agency (or its pharmacy benefit manager) and the retail pharmacies under which the retail pharmacies agree to act as a purchasing agent or prime vendor for the Federal agency. Such contracts would be prerequisites to a Federal procurement, which in turn is a prerequisite to a depot contracting system under the VHCA. PhRMA respectfully requests a full explanation of the basis for the Proposed Rule's conclusion that a Federal Agency Retail Pharmacy Program, if compliant with the procedures set forth in the proposed clause, would qualify as a depot under the VHCA.

The GSA Lacks Authority To Interpret the VHCA. The GSA, and not the VA, issued the Proposed Rule that purports to interpret the VHCA. While the VA did issue a letter to covered drug manufacturers in October 2004 that ostensibly authorized the DoD's TRICARE Retail Pharmacy Benefit ("TRRx") Program, that letter was not published for notice and comment.[24] Moreover, the VA, and not the GSA, is responsible

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[23] *PG&E Transmission, Northwest Corp. v. Fed. Energy Regulatory Comm.*, 315 F.3d 383, 386 (D.C. Cir. 2003) (Agency must be able to demonstrate that it has made a reasoned decision based upon substantial evidence in the record and articulate a satisfactory explanation for its actions including a rational connection between the facts found and the choice made.).

[24] 5 U.S.C. § 553.

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for interpreting the VHCA.[25] The VA, and not the GSA, should publish rules for notice and comment to the extent that those rules are premised on a substantive interpretation of the VHCA. The GSA interpretations of the VHCA are not entitled to legal deference.

The VHCA Does Not Authorize Federal Agencies To Obtain FSS Pricing. Independent of the Master Agreement and PPA mandated by the VHCA, manufacturers and the VA also establish FSS prices for drugs sold under the FSS contracts. FSS prices are developed pursuant to the terms and conditions of the FSS contract solicitations.[26] As the Proposed Rule acknowledges, the FSS price for a drug can be lower than the drug's FCP.[27] The VHCA does not authorize Federal agencies to access FSS prices for their depot contracts. Nor does the VHCA permit Federal agencies to collect rebates from manufacturers. Instead, as noted, the VHCA only allows the Big Four agencies to acquire covered drugs through a depot contracting system at a statutorily-mandated discounted price that is no higher than the FCP (not the FSS). To the extent that the VHCA is cited as support for the payment of rebates designed to approximate FSS pricing, the clause would thus be invalid. The GSA should clarify that it is not relying on the VHCA for its proposal to require payment of rebates based on the FSS prices for retail pharmacy purchases.

2. The Federal Property and Administrative Services Act ("FPASA"), 40 U.S.C. § 501 and 41 U.S.C. § 259(b)

Summary of FPASA. The preamble to the Proposed Rule also cites two sections of the FPASA, apparently as support for part or all of the rule and the proposed supplemental GSAR clause. The first cited provision, Section 201(a) of FPASA, authorizes the GSA to "procure and supply personal property and nonpersonal services for executive agencies to use in the proper discharge of their responsibilities."[28] The

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[25] *See* TRICARE, Federal Pricing Forum Questions (answering questions raised at the May 11, 2004 Industry Conference re: TRRx), *available at* http://www.tricare.osd.mil/pharm_mfg/downloads/FederalPricingForumQuesAns_Final.pdf (posted Oct. 28, 2004) ("GSA does not have jurisdiction over TRICARE or the application of Federal ceiling prices to TRRx under [the VHCA]").

[26] Price Reductions (May 2004), 48 C.F.R. 552.238-75.

[27] 70 Fed. Reg. at 19,050.

[28] 40 U.S.C. § 501(b)(1)(A).

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second cited provision, Section 309, is a FPASA definitional section that includes procedures established by the GSA for the award of multiple award schedule contracts (such as FSS contracts) within the definition of "competitive procedures" if: (1) participation in the multiple award program is "open to all responsible sources"; and (2) contracts awarded through the GSA procedures result in "the lowest cost alternative to meet the needs of the government."[29] Thus, Section 309 provides that "competitive procedures" are those procedures under which an "executive agency" enters into a contract pursuant to full and open competition, and that the term "competitive procedures" can include those procedures adopted by the GSA relating to the award of multiple award schedule contracts.

Congressional Purpose of FPASA. The purpose of FPASA is to empower the GSA "to provide the Federal Government with an economical and efficient system for . . . procuring and supplying property and nonpersonal services."[30] Congress authorized the GSA "to regulate the policies and methods of executive agencies with respect to the procurement and supply of personal property and nonpersonal services."[31] For purposes of FPASA, the term "procurement" means "all stages of the process of acquiring property or services, beginning with the process for determining a need for property or services and ending with contract completion and closeout."[32]

FPASA Does Not Authorize the Proposed Rule. Neither of the two FPASA provisions cited by the GSA (nor any other FPASA provision) authorizes the Proposed Rule. As noted, FPASA permits the GSA to establish procedures that govern the procurement of property and services for use by executive agencies. For the reasons described in the discussion of the VHCA above, the retail pharmacy program authorized by the Proposed Rule does not involve Federal procurement of the covered drugs that would pass through the retail pharmacy program. Accordingly, the cited FPASA provisions do not apply.

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[29] 41 U.S.C. § 259(b).

[30] 40 U.S.C. § 101.

[31] H.R. Rep. No. 670, 81st Cong., 1st Sess. (1949), *reprinted in* 1949 U.S. Code Cong. & Admin. News 1475.

[32] 41 U.S.C. § 403.

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Moreover, FPASA does not contemplate the establishment of procedures, such as those in the Proposed Rule, under which a Federal agency's instruction to a retail pharmacy to use its commercial inventory to fill a prescription for an agency beneficiary could be deemed an order under an FSS contract of the drugs used to fill the prescription. As described in section B below, an order must be placed "directly with the contractor in accordance with the terms and conditions of the pricelists."[33] Deemed orders do not meet this requirement. In short, there is no nexus between FPASA and the Proposed Rule's provision that an instruction from a Federal agency to a retail pharmacy can substitute for an authorized entity's order under an FSS contract.[34]

The GSA's Prior Interpretations of FPASA Do Not Permit Agency Instructions to be "Deemed" Orders under FSS Contracts. The GSA has issued an order (the "GSA Order") that identifies the entities and organizations that are eligible to order supplies and services from FSS contracts.[35] The GSA Order confirms that FSS contracts can be used to "procure and supply personal property and non-personal services for executive agencies and other Federal agencies, mixed-ownership Government corporations as identified in the Government Corporation Control Act, the District of Columbia, and qualified nonprofit agencies for the blind or other severely handicapped for use in making or providing an approved commodity or service to the Government."[36] The GSA Order also explains that other organizations may be eligible to order from the FSS pursuant to other sections of FPASA or "by reason of enabling statutory authority."[37]

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[33] FAR § 8.406-1.

[34] *See Liberty Mut. Ins. Co. v. Friedman*, 639 F.2d 164 (4th Cir. 1981) (citing *Chrysler Corp. v. Brown*, 441 U.S. 281, 308 (1979)) (To establish that a regulation is promulgated pursuant to power conferred by Congress, there must be a "nexus between the regulation[] and some delegation of the requisite legislative authority by Congress.").

[35] GSA Order ADM 4800.2E (Jan. 3, 2000) ("GSA Order").

[36] GSA Order at ¶ 3.

[37] GSA Order at ¶ 3; *accord, id.* at ¶ 7 ("Organizations are eligible to use GSA sources of supply and services pursuant to the Property Act or other statutory authority"). The Scope of Contract clause in the FSS contracts recognizes a further potential limitation: an FSS contractor is not obligated to accept orders that are not "received from activities within the Executive Branch of the Federal Government." *See* I-FSS-103 Scope of Contract – Worldwide (July 2002). Thus, although approved cost reimbursement contractors can order from the FSS, the FSS contractor is not required to accept orders from those cost reimbursement contractors.

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The GSA Order confirms that authority under a statute or a properly issued regulation – *i.e.*, a regulation that is within the scope of existing statutes and that does not conflict with acquisition regulations – is required before a new entity can be granted access to the FSS. As discussed above, the drugs dispensed through a Federal Agency Retail Pharmacy Program would be purchased by an agency beneficiary and filled from the retail pharmacy's commercial inventory. The drugs would not be ordered by an executive agency under an FSS contract. The Proposed Rule is thus not consistent with the GSA Order. Moreover, the expansive concept of a "deemed" order (in lieu of an actual order) that underlies the Proposed Rule could set a dangerous precedent that could apply to FSS contracts for other products, and thereby result in a slippery slope that could undermine the integrity and upset the economics of the GSA FSS contracting system. For these reasons, implementation of the Proposed Rule would violate FPASA and would exceed the GSA's authority.

3. National Defense Authorization Acts of 1999 and 2000, 10 U.S.C. § 1074g

Citing the National Defense Authorization Acts of 1999 and 2000, the preamble to the Proposed Rule also suggests that the Proposed Rule is "required by DoD in order to reengineer its TRICARE Pharmacy Benefits Program."[38] The cited authorization statutes directed the DoD to "establish an effective, efficient, integrated pharmacy benefits program" and to incorporate "the best business practices of the private sector" in implementing the program redesign.[39]

No provision in either of these authorization statutes would allow the GSA to extend the scope of FSS contracts in the unprecedented manner proposed in the rule. Rather, these statutes required the DoD to develop a uniform formulary through which its beneficiaries would be able to receive a uniform and integrated health benefit throughout the three points of service in the TRICARE health system: Military Treatment Facilities ("MTFs"), the TRICARE Mail Order Pharmacy ("TMOP"), and retail pharmacies. The DoD promulgated regulations implementing these statutory requirements in April 2004.[40]

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[38] 70 Fed. Reg. at 19,046.

[39] 10 U.S.C. § 1074g(a). This statute applies only to the DoD. It would not have any bearing on a retail pharmacy benefit offered by the VA, the PHS or the Coast Guard.

[40] 69 Fed. Reg. 17,035 (Apr. 1, 2004).

G501-1

Under those regulations, TRICARE beneficiaries who purchase their drugs in network retail pharmacies are required to pay $3 for a 30-day supply of generic drugs; $9 for a 30-day supply of drugs that the DoD Pharmacy and Therapeutics ("P&T") Committee determines to meet its standards of clinical and cost effectiveness; and $22 for a 30-day supply of drugs that the P&T Committee determines not to meet its standards of clinical and cost effectiveness. For those same cost shares, a TRICARE beneficiary can obtain a 90-day supply of the same prescription drugs through the TMOP. TRICARE beneficiaries do not pay a cost share for drugs obtained in MTFs.

The Proposed Rule would not affect these beneficiary cost share requirements or increase beneficiary access to prescription drugs. It would, however, reduce the DoD's costs for covered drugs that are dispensed in network retail pharmacies. Thus, finalization of the Proposed Rule could incentivize the DoD to promote utilization of the retail pharmacy point of service, where the DoD has set higher beneficiary cost-sharing amounts. Contrary to helping beneficiaries to obtain affordable medicines, the Proposed Rule could have the opposite effect.

We also do not believe that expansion of FSS contract pricing in the manner suggested in the Proposed Rule would be consistent with the "best business practices of the private sector." Rather, expansion of the FSS contracts to commercial sales in the manner suggested in the Proposed Rule would directly conflict with private sector practices. Federal pricing, including the Price Reductions clause in the FSS contracts and the price ceiling mandated by the VHCA, does not apply in the private sector and is not a commercial business practice.

The business practices of the private sector do include a number of models that are available to the DoD (and other Federal agencies) that could be used to help contain drug acquisition costs. For example, it is commonplace in the private sector for purchasers or their agents to negotiate rebate agreements with manufacturers and use a variety of tools to achieve cost savings.[41] Such a system could work well within the DoD and would be consistent with what Congress intended when it directed the DoD to

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[41] The DoD's PBM apparently is prohibited by contract from negotiating or collecting rebates of any type from pharmaceutical manufacturers. Contract MDA 906-03-C-0019 at 5 (Sept. 26, 2003). This contract provision may be inconsistent with the statutory requirement that the DoD incorporate "the best business practices of the private sector" into its TRICARE healthcare system.

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incorporate the best business practices of the private sector into its TRICARE health system.[42]

B. The Proposed Rule Is Inconsistent with the FAR

The "deemed order" requirement of the proposed "Federal Agency Retail Pharmacy Program" GSAR clause also would be invalid because it directly conflicts with the Federal Acquisition Regulations ("FAR"). Among other clauses, FAR 9.403 ("Definitions") expressly lists reimbursement transactions, such as insurance and government subsidies, within the definition of "nonprocurement transactions." By contrast, the Proposed Rule concludes that Federal agency reimbursement of a prescription drug claim made by one of the agency's beneficiaries constitutes a "procurement" transaction under the FSS contract and/or a depot contract. The Proposed Rule's conclusions in these regards are in direct conflict with the FAR.

Similarly, FAR 8.406-1 ("Order Placement") provides that an "ordering activity shall place an order directly with the contractor in accordance with the terms and conditions of the pricelists" and then proceeds to specify the terms that must be included in the order. Under the Proposed Rule, however, no order would be placed "directly" with the FSS contractor. Instead, orders would be "deemed" to occur when a Federal agency instructs the retail pharmacy to fill a prescription order requested by one of the Federal agency beneficiaries, a transaction to which the FSS contractor is not a party and over which it has no control.

The proposed clause tries to avoid this conflict with the FAR's ordering provisions, at least in part, by declaring in subsection (a) that certain FAR clauses that are not consistent with the proposed clause would not apply to Federal Agency Retail Pharmacy Programs.[43] However, this approach would be insufficient. The FAR precludes agencies from promulgating supplemental acquisition regulations, such as the proposed clause, unless they are: (a) necessary to implement FAR policies and procedures within the agency; or (b) additional policies, procedures, solicitation

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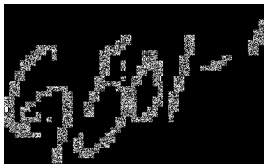
[42] *See* Gen. Accounting Off., Pub. No. GAO/HEHS-98-176, Defense Health Care: Fully Integrated Pharmacy System Would Improve Service and Cost-Effectiveness 37 (June 1998) ("TRICARE contractors . . . are less able to negotiate deeper price discounts from drug companies without the ability to provide preferred or favorable status on a closed or incentive-based drug formulary").

[43] 70 Fed. Reg. at 19,050.



Non-FAMP CalculationConsiderations

- If TRRx sales included product delivered through wholesalers (as opposed to direct sales to pharmacies) and Mfa uses wholesale sales to compute non.FAMPs, then these TRRx sales and units must be removed from wholesale sales during current non.f AMP calculauons
- If products sold to TRRx were originally booked as direct saJes to a retail chain, it is likely that these sales were already excluded from the non..F AMP calculation
- Jfthe TRRx transactions cause anomalies in the non-fAMP that are not taken care of through the normal chargeback smoothing methodology, communicate those issues to Me) Noel at the National Acquisiuon Center for consideration.

Non-FAJ\fP Impact Scenario.

. Scenario 1, Method 1
  - Manufacturer sells only to WholesaJers
  - Manufacturer has no contractual agreements with the retail pharmacies - Manufacturer nonnanv removes FederaJ saJ~ by adjustinll wholesale sales at contraCt selJimz price. in this case the assumed FCP of $72
  - In absence of known saJe price to TRRx NetWOrk. the manufacturer calculates TRRx refund using Non.FAMP = 594.74
  - TRRx reports to manufacturer that retail pharmacies purchased J ,250 units of the NDC
  - Given the asswnptions the actual refund to Tricare would be J ,250 x ($94.74-$72.00) ... $28,425
  - When the manufacturer does not know the price to the retailer, the rerw:.. amount to Tricare that was figured based aD nOD..FAMP cannot be used 10 rc-state the nou.FAMP. - The amount used to restate the non.f AMP must be at WAC.
  - The fact that Tric81e has given Manufacturers a lesser price (Non-f AMP) to calculate the refund CaMot transJate to an assumption that the original sale occurred at other than WAC

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. Chanles to non-FAMP (Scenario 1, Method 1)

- Government sales at FCP are increased by 1,250 units at $72.00, units are increased by J ,250
- An additional reduction is made to account for the TRRx refund wbich is the difftrence between WAC and the FCP times the number of units or ($100-$72) x] ,250 - $35,000

Orilln.. CalcuJatioD

	DoBars	Units
Wholesale SaJes (WAC - $100)	$10,000,000.00	100,000
Less:		
Prompt Pay Discount (2">	$200,000.00	
Government Sales 0 $12.00	5360,000.00	5.000
PHS (0 602 price $75.00)	$2,250.00	30
Chargebades	5523,075.00	
SubtotaJ Reductions Non-FederaJ DoUars &I Units non-FAMP	$1,085,325.00	
	$8,914.675.00	94,970
	$93.87	

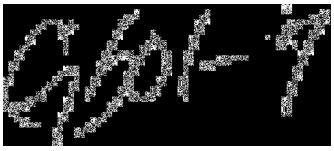
Revised CalculatioD

	DoUars	Units
WholesaJe SaJes (WAC" $100)	$10,000,000.00	100,000
Less:		
Prompt Pay Discount (2">	$200,000.00	
Government Sa)es ▪ snoo	$450,000.00	6,2501
PHS (0 602 price $75.00)	$2,2S0.00	30
Chargebacb	5523,075.00	
TRRx Refund. WAC	535.000.00	
Subtota] Reductions Non-Federa) DoBus &I Units non-FAMP	*$1,210,325.00*	
	$8,789,615.00	93,720
	$93.79	

. Scenario 1, Metbod :z

- Manufacturer seUs onJy to WhoJesaJm
- Manufacturer has no contractuaJ agreements with the retaj) pharmacies
- Manufacturer nonnaJlv removes Federal *sales bv* adiustina wholesale sales and c:haflzebacks
- The FCP - $72
- In the absence of known seJes price to TRRx NetWork, Manufacturer uses

Non-FAMP a= $94.74



. Changes to non.FAMP (Scenario 1, Method 2)

- Govenunent sales at "WAC" is increased by],250 x $100.00, Units are increased by 1,250 - The TRRx refund for bookkeeping purposes is calculated as in Method I. - No further adjustment js necessary because the chargeback system is not affected by the transaction.

Orieinal CaJcuJatioD

	DoDars	Units
WholesaJe Sales (WAC. 5100) Less:	$10,000,000.00	100,000
Prompt Pay Discount (2")		
Government Sales (0 WAq PHS	$200,000.00	
(OWAq	$500,000.00	5,000
Chargebacb	$3,000.00	30
(Less Gov and PHS Chargebacks)	*$523,0'15.00*	
Subtotal Reductions	-$1.0,750.00	
Non--FederaJ DoDars &r Units	51,085,325.00	
non.FAMP	58,914,675.00	94,970
	$93.81	

Revised CaJ~uJatiOD

	DoDus	Units
WhoJesaJeSaJes (WAC. $100) Less:	$10,000,000.00	100,000
Prompt Pay Discount (2">		
Government SaJes CO WAq PHS (0	5200,000.00	
WAq	$625,000.00	6,2501
ChugebacJcs	$3,000.00	30
(Less Gov and PHS aarlebacks)	5523,075.00	
Subtobd RedUCtioN.	-$140,750.00	
NOJ1o.federaJ DoDars at Units	$1,210,325.00	
non.FAMP	$8,789,675.00	93,720
	593.79	

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- Scenario 2, Metbod J

  - Manufacturer sells onJy to Wholesalers
  - Manufacturer has agreement with the retail pharmacy at 8 sales price of 595.00
  - Manufacturer normallv removes Federal sales bv adiustinR wholesale safes at Government contract seJling urice. in this case the FCP t:: $72
  - TRRx rcpons to manufacturer that retail pharmacies purchased] ,250 units of the NDC
    - Given the assumptions (wholesale sales only, known contract price to retail pharmacy) the actual refund to Tricare would be 1,250 x (595.00 572.00).528,750 .
  - When the manufacturer knows the price to the retailer, those transactions wi)) need to be replaced with Tricare transactions.

- Changes to non.FAMP (Scenario 2, Metbod 1)

  - The chargeback transactions are decreased by the charge backs for those urnts now cJassified as Tricare (1,250 x 55.00 ., 56,250)
    - An additional reduction is made to 8CCOWlt for the TRRx refund which is (for bookkeeping pwposes in this scenario) the difference between WAC and the FCP times the number of units or ($100.$72) x],250 - 535,000
    - The fact that Tricare has given Manufacturers a lesser price (pharmacy contract price) to calculate the refund cannot translate to an assumption that the original sale occuncd at other than WAC.

Orielna) Calculation

	Donars	Units	
WholesaJe Sales (WAC. 5100)	510,000,000.00	100,000	
Less:			
Prompt Pay 1)jscount (2)	5200,000.00		
Goverr.ment Sales. $'72.00	S360,000.00	5,000	.,- .
PHS (0 602 price $75.00)	52,250.00	30	,.... .
Chargebacks	$523,075.00		
Subtotal Reductions	51,085,325.00		
Non-Federal Dollars at Units	$8,914,675.00	94,970	
non.FAMP	$93.81		

Revised Calculation

	Do11an	Units
Wholesale Sales (WAC. $1(0)	510,000,000.00	100,000
Less:		
Prompt Pay Discount (2")	$200,000.00	
Government Sales 0 $72.00 PHS	$450,000.00	6,2501
(0 602 price $15.00)	52,250.00	30
Chargebadcl	$516,825.00	
TRR:x Refund 0 WAC	535,000.00	
Subtotal Reductions	$J,204,075.oo	
NOr1*Federal DoUars at Units	$8,795,925.00	93,720
non-FAMP	593.85	

. Sccnario 2, Meihod 2

- Manufacturer sens onJy to WhoJesaJers
- Manufacturer has contrnctua1 agreements with the retaH pharmacies at a sales price of $95
- Manufacturer nonnallv removes Federal sales bv adiustinll wholesaJe saJes and chareebacks
- The fCP = $72; Non-f AMP = $94.14

. Chanaes to nOD..FAMP (Scenario 2, Method 2)

- Government sales at "WAC" is increased by 1,250 x $100.00, Umts are increased by *I,2S0* - The TRRx refund for bookkeeping purposes is calculated as in Method 1. - No further adjustment is necessary because the cbargeback system is not affected by the transaction

Orfldnal Calc:ulatfoD

	DoUIJ'I Units	
WholesaJe SaJes (WAC. $100) Less:	$10,000,000.00	100,000
Prompt Pay Discount (2%)	5200,000.00	
Government Sales (0 W Aq PHS	$500,000.00	5,000
(OWAq	53,000.00	30
Chargebacks	$523,015.00	
(Less Gov and PHS Chargebacks)	.$140,750.00	
Subtotal Reductions	$1,085,325.00	
Ncin-FederaJ DoDars at Units non--FAMP	58,914,675.00	94,970
	$93.81	

Revised CalcuJatioD

	DoUan Units	
WhoJesaJe Sales (WAC - $]00) Less:	$1£1,000,000.00	
Prompt Pay DiscOUJ\t (2%)	100,000	
Government Sales (0 WAq PHS	5200,000.00	
(OWAq	$625,000.00	6.250]
Chargebacks	$3,000.00	30
(Less Gov and PHS O\argebacks)	$5]6,825.00	
Subtotal Reductions	-$140,750.00	
Non-FederaJ DoUars ar Units non-FAMP	$1,201,075.00	
	$8,795,925.00	93,720
	$93.85	

WHITE PAPER FOR THE OFFICE OF THE SECRETARY
TRICARE AND FEDERAL CEILING PRICES

OCTOBER 10, 2002

PURPOSE:

To inform the Secretary of the facts and circumstances surrounding a decision of the VA P.L. 102-585, Sec. 603, Policy Group at Its September 24,2002, annual meeting regarding requests for favorable Interpretation of the P.l. received from DoD's TRICARE Management Activity (TMA) between September 17,2001, and June 28, 2002. TMA has asked that VA concur In Its opinion that purchases of covered drugs under the retail portion of the new TRICARE Phannacy Benefits Program (TPSP) qualify for Federal Ceiling Prices (FCP) under the P.L. (Veterans Health Care Act of 1992; 38 U.S.C. 8126).

POLICY GROUP DECISION:

After considering TMA's position and a PhRMA letter opposing the Idea, the Policy Group agreed that TMA's interpretation of the P.l. was reasonable and that DoD beneficiary prescriptions filled under the retail portion of the new TPBP
will qualify for Federal CeDing Prices. (The Policy Group Includes representation
from all the elements of VA that are stakeholders In the drug pricing statute, i.e., VHA's. PBM, OA&MM's NAC, the OffICe of Inspector General (52C), and the Office of General Counsel (025).

DISCUSSION OF LEGAL QUESTIONS:

There can be no real question that, when Congress .enacted P.L. 102-585, Sec. 603, in 1992, their Inclusion of DoD as. one of the benefiting Federal activities meant that Congress expected aD CoD expenditures for covered drugs to be affected by the calculations which yield Federal Ceiling Prices. The questions that arise have to do With the strict or liberal interpretation of the statute's wording that describes the acquisitions that are the subjects of a Master Agreement (MA) and Phannaceutical Pricing Agreement (PPA). The statute, at Sec. 8126{aX2), sots forth one *01* the requirements of the MA as follows: "with respect to each covered drug of the manufacturer procured by a Federal agency described In subsection (b) pncludlng. CoD) on or after January 1, 1993, that is purchased under depot contracting systems or listed on the Federal Supply Schedule, the manufacturer has entered Into and has in effect a pharmaceutical
pricing agreement with the Secretary....

The prlmarv legal Issue Is whether II DoD Pharmacy Benefits Office (PSO) mochanlsm for filling DoD beneflclarv prescriptions throuah a commercial retail phannacy network and contracted pharmacy benefits management firm (PBMJ constitutes a Durchas8 by DoD' under II depOt contractlna sYStem.

1. The definition of depot in Sec. 8126(h)(3) asserts that "depor means a "centralized commodity management system through which coyered drugs procured by an agency of the Federal Government are- (A) received, stored, and delivered through- (i) a federally owned and operated warehouse system, or (iI) a commercial entity operaUng under contract with such agency; or (B) delivered directly from the commercial source to the entity using such. covered drugs." TMA's TPBP does not Involve a federally owned and operated warehouse system, and, while it does Involve a commercial warehouse system, that system does not have a direct contract with DoD. Nevertheless, prong (B) of the definition is broad enough to Include the TMA plan. The commercial prime vendor or warehouseman serving the pharmacies can certainly be considered a commercial source, and the dispensing retail pharmacy fits within the description "entity using such covered drugs". This very broad language was most likely adopted by Congress to accommodate possible future pharmaceutical distribution techniques deyeloped in this country and ultimately participated in by
the Government. The TPBP is one such covered drug prescription distribution method.

2. Under TMA's plan, the acquisition of beneficiary prescriptions is a procurement by DoD. TPBP Is a centralized system, I.e., "depot", for the acquisition, delivery, and distribution of Prescriptions by DaD on behalf of its beneficiaries throUgh the use of a DaD PBO and a contracted PBM with a retaD pharmacy network. Additionally, 000 appropriated funds will be used by the PBO
and PBM to pay for all TRICARE prescriptions and the PBM will be paid a negotiated administrative fee for petfonnance of all services under the contract, including providing the retail pharmacy network and functioning as a fiscal intermediary for DoD. The PBM fee will not be related directly or indirectly to total phannaceuticat costs. The PBM will Issue DoD appropriated funds (based on a letter of credit against a government account and authorized by the PBO) to pay for each TRICARE prescription, after receiving PBO's verification of the individual beneficiary's eligibility.

The filling of DaD beneficiary prescriptions at non-network retail pharmacies not

under contract to the PBM would not qualify as a DaD procurement through a

"centralized commodity management system." and therefore is not eligible for FCP.

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3. VA has always believed that implied in the statlte are the propositions that covered drugs purchased by the named Federal agencies at the statutory discount are not Intended to provide the Govemment or its contractors with an opportunity to make a profit at the expense of drug manufacturers and are not intended to offer commercial heahh care organizations access to Federal pricing indirectly through the diversion of the discounted drugs to them for use in the commercial maltel. TMA's TPBP satisfies these implied statutory policies through the wolt of the proposed CoD PBa using a sophisticated Phannacy Data Transaction System (POTS) that will, be linked to OEERS to ensure that non-DaD beneficiaries do not receive discounted prescriptions outside of TRICARE's parameters. The problem of possible diversion Is almost completely eliminated because the TPBP would never put actual discounted drugs In the hands of a retail pharmacy. The latter would merely use Its nonnal stocks of drugs, and CoD would receive the discount on the back end after Its PBO submits utilization data to the manufacturers. Also, TPBP is not properly described as an Insurance scheme because PBa software is used to approve prescriptions for every requesting beneficiary and DoO appropriated funds are used to pay for these prescriptions through PBM's efforts as agent of DoD. The only major difference between this model and the pharmaceutical supply contracUphannaceutlcal prime vendor models that VA and *DaD* use for their own hospitals is that, under the TPBP, DoO requests a discount in the form *ot* a rebate rather than up front at the time of the original purchase of the drug for the beneficiaries.

FACTUAL BACKGROUND:

Ever since CoD implemented its TRICARE program through the award of managed health care delivery contracts to civilian contractors for various regions of the United States In the mid-1990's, the office of CoD's Assistant Secretary for Health Affairs (OASHA) has been seeking to apply the pricing benefit of the P.L. to prescriptions fDled for beneficiaries by commercial subcontractors of the TRICARE contractor. After an exchange of correspondence with DoO's OGC and a lengthy discussion within VA OGC as to the appticability of the P.L. to prescriptions filled through retail pharmacies as part of a capitated managed health care contract that was not strictly cost based, VA OGC published on October 7, 1996. a "Dear Manufacturet' lettel containing guidance for manufacturers *of* covered drugs on several aspects of P.L. administration. The contents of the letter had been approved by the P.L. PoHcy Group.

Paragraph 3 of the letter to industry Informed manufacturers of the Interaction between VA and CoD concerning the possible eligibility of TRICARE contractors for FCPs. The MOear Manufacturer" letter then stated:

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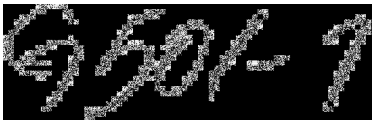

-An exchange of infonnation between the OffICes of General Counsel
of DaD and VA has resulted In VA taking the position that the VHCA
[P.L.] does not require manufacturers to make FCPs available to the presently awarded TRICARE oontractors on orders placed by them or by their commercial pharmacy subcontractors for distribution through retail pharmacies. VA cannot conclude that such oovered drug purchases under the TRICARE program, as presently structured, constitute covered dl\lQ procurements by the DoD within the wording of the act. Major factors In this conclusion are the absence of any direct CoD payment for invoiced phannaceutlcal products and the lack of any way to trace pharmaceuticals purchased by a TRICARE contractor or subcontractor back to DaD on an Item-by-item basis:

DoD reacted to VA's "Dear Manufacturer-letter by proposing that legislation be enacted to amend Title 10 of the United Stated Code to specifically bring the procurement of

phannaceuticals on behalf of CoD by an authorized contractor through an authorized

retaU phannacy network or maN order program within the purview of 38 U.S.C. 8126.

This proposal was never enacted into law, apparently as a result of industry's hostility to

it when it was sent to Capitol Hill.

Subsequently, TMA, DaD O~C, and DoD OASHA representatives held discussions with
counterparts from VA to discuss how FCPs could be obtained for the increasingly large TRICARE retail phannacy expenditure. As an outgrowth of these discussions, TMA decided to carve the phannacy benefit oomponent out of its solicitations for the second round of regional TRICARE contracts and to create a CoD Pharmacy Benefit OffICe (PBO) that would be responsible for contracting with a commercial pharmacy beneftts management finn (PBM) (and, through It, with a retail phannacy network) which would serve as the PBO's agent for the procurement and dispensing of drugs for TRICARE beneficiaries outside of the military treatment facility system. This new approach was unveiled to VA In August 2001, and to industry In a general way at a pre-solicitation conference in September *2001.* A description of the proposal, along with a diagram, was included in a letter from TMA's General Counsel to VA's Assistant General Counsel (025) on September 17. 2001.

The new TRICARE Pharmacy Benefit Program (TPBP) was considered by the VA Public Law Policy Group at its 2001 annual meeting, but questions were raised which

required additional clarification. In November *2001,* 025 wrote to TMA's General

Counsel posing certain questions related to statutory Interpretation and the practical operation of the TPBP. TMA answered these questions on February 12, 2002, at a meeting on April 23, 2002, and in a follow-up letter of June 28, 2002.

On September 24,2002, the P.L. Policy Group reviewed all the correspondence and notes and concluded that TMA's interpretation of the P.L. as It applied to the TPBP was more reasonable than the opposing interpretation suggested by PhRMA.

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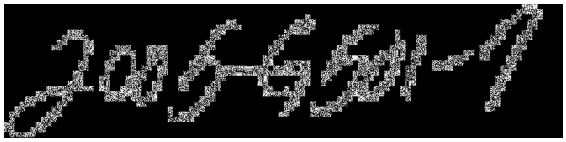

DELEGATIONS WITHIN VA:

When VA was in the process of Implementing the P.l. at the end of 1992 and the first half of 1993, there was a division of responsibUities. Since VHA's budget was the ultimate beneficiary of VA's participation In the statutory scheme, VHA's Drug and Pharmaceutical Product Management section (D&PPM) was given the responsibility of receiving and maintaining the annual reports of non-Federal Average Manufacturer Prices (Non-FAMP) for every covered drug that yield the FCPs for the following calendar year. On November 23, 1992, then Acting Secretary Principi signed a delegation to the Deputy Assistant Secretary for Acquisition and Materiel Management, giving him the authority to sign and administer Master and PhannaceuticaJ Pricing Agreements, with the authority to re-delegate as appropriate. On July 12. 2001, the Deputy Assistant Secretary for Acquisition and Materiel Management made a second re..<felegatlon or his authority to the Assistant Director, Pharmaceutical, Dental and Other Schedules, Federal Supply Schedule Service at the VA National Acquisition Center. This delegation superseded all previous delegations including the original one to the Chief, Pharmaceutical Products Division at the NAC.

On July 29, 1993, Deputy Secretary Gober signed a delegation document giving the authority to receive and rule on discretionary FCP Increase applications to an FCP Nomlnaf Increase Board consisting of anOGe attorney (025), Chief, Drugs and Pharmaceutical Products Management (119), and a VA *OIG* Audilor .chosen by the Director of Contract Audits (53C). Authority to hear and detennine appeals from an adverse decision of that Board was delegated to the VA Board of Contrad Appeals, whose decision shall be final. In the spirit of this delegation, the Public Law Policy Group was constituted by 025, the delegated administrative officials, and the OffIce of Inspedor General (53C) to meet at least annually and reach collegial resolution of significant issues of administration arising under the statute. The Policy Group has met in September or earty October of every year beginning In 1993 and has adopted almost all of its resolutions by consensus.

CONCLUSION:

For the above reasons, covered drugs purchased in the form of ODD beneficiary prescriptions under the retail portion of the new TPBP do qualify for Federal Ceiling Prices because, under the plan submitted to us, such purchases will be a procurement by DoD under a depot contracting system as defined In 38 U.S.C. 8126(h)(3).

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[redacted]

DEPARTMENT OF VETERANS AfrAJRS
Office of General Catinsel
PoSt Office Box 16
Hines IlSO'..'

December 30, 1992

Via Facsimile' U.S. Mail

In Reply Rele, To:

025

Dear Manufa.c:'turer:

We have received your request for an increase in the Federal ceiling price of yow: pha.:m4ceuti.cal product pursuant to the requirements of the Veterans Health Care Act of 1992 (the "Act"). The Act at 38 U.S.C~ 8126(a)(2) states that the price paid by the specified Federal agencies ..... .may nomJ.nally exceed the Federal ceiltng price (PCP) "if found by the Secretary to be in 1:he best intere,a of the Deparuaent or such Federal agencies.. VA has determined thAt, in most instances, the statutory teDI .~nnti ft~ 11y exceed" does not allow any increase that exceeds lD' of the IIIOst recently reported annual non-FAHP.

In order to initiAte the processing of A request for nominal increase in the Pederal ceiling price, a manufacturer muSt submit a. detailed. writ1:en request JUStifying the .increase for each separate Covered drug item and a certification by its President stating that the FcP is below the production cost of that covered drug and selling at that price would cause the manufacturer 1:0 lose money on ~ts overall business. The manufacturer also must: agree 't:O make - full disclosure of relevant company records 1:0 enable VA to verify the accuracy of the certification (see enclosed certification).

Shoula the Secreta%)' decide 1;0 grant t:.he ceiling price increAse, this amount vill be added to the FCP. If the addi.t.LQI1 of the nODtinal amount does not result in a posiuve

number, the ceiling price will be set At $.01. Thank you for your cooperat:ion with our efforts to l.mplement the new Ac.t. It you have any further guestions, please do not hesitate1:Q call (708) 216-2505.

Sincerely yours,

:,,:,-::'c\~ ":1...~"" _,__

~ -William E. Thomas, Jr.
Assistant General Counsel

CEaTIFICATION

I, *I* (President of the company), hereby certify that: I am the .President of (the Ho.nufActw:er) *I* (adctresli) and that: I have the authority to execn1:e this cert:ificat:ion for, and on behalf of (lJanufaCturer). I certi£y that the current Federal ce.i.ling price of (fill in name of product) is below the cost,.of produc.i.ng this covered drug.

I certify that selling t:he Above covered,. drug product to the Department of Veterans A.ffaUa, Department: of Defense, and Public Health Service, including tb.e :r~tth'l\ Health Service at: t.bia price will cause (Kanufacturer) to loae money an its overAl.l busim!tsa. I fUrther Certify that (lfanufact:urer) I will make full disclosure of relevcnt financ.iAl records and that any representa1:ivea of the GoveDmlent shAJ.l have the right to f'1e and audit any anc1 all/recorda and relAted documents necessuy to verify the val.id.ity of my S1:41:e11ent:a.

S1.qnat:ure Date

Tit:le

Merck & Co., Inc.
P. O. Box 1000
North Wales, PA 19454

VIA E-mail and FAX

June 11, 2005

Mso Laurieann Duarte
General Services Administration
Regulatory Secretariat (VIR) 1800 F
Street, NoW., Room 4035
Washington, DoC. 20405

Re: GSAR Case No. 2005-G501

Dear Ms. Duarte:

Merck & Co., Inc. ("Merck") appreciates the opportunity to comment on the above-referenced issued in the April 12, 2005, *Federal Register.* Merck is one of the largest manufacturers and suppliers of pharmaceuticals to the Federal government, in particular to the Department of Defense and the Department of Veterans Affairs. Merck recognizes and greatly values the sacrifices and contributions of our service members and is committed to help assure that they and their families (and all Americans) have access to necessary medicines and the highest quality health care. Further, Merck is sensitive to the budgetary constraints cited as a basis for the Proposed Rule, but believes that the most effective means to control healthcare costs (to include drug prices) is the competitive marketplace, not price controls. Merck opposes the Proposed Rule because we do not believe that it is the best way to make high quality healthcare available to DoD beneficiaries and because we have concerns about its legal underpinnings and implementation challenges. Therefore, we urge GSA to withdraw the Proposed Rule.

Merck does not believe that the Proposed Rule is consistent with Congressional intent under Section 603 of the Veterans Healthcare Act ("VHCA"). The legislative history shows that Congress intended to extend the Federal Ceiling Prices ("FCP") authorized by VHCA to pharmaceuticals procured by government through only two types of procurements: Federal Supply Schedule ("FSS") contracts and depot contracts. Congress did not intend - and VHCA does not authorize - the extension of FCP to other types of procurements or to those purchases that arc not procurements, *e.g.*, reimbursements of prescription claims.

The Proposed Rule would establish a supplemental General Services Administration Regulation ("GSAR") concerning pharmacy benefit plans ("Federal Agency Retail Pharmacy Programs") of the "Big Four" agencies (V A, DoD, Public Health Service and the Coast Guard). Incorporation of the proposed supplemental GSAR into Federal Supply Classification ("FSC") Group 65 FSS contracts would require FSS holders (such as Merck) to pay "refunds" to the Big Four agencies on sales to beneficiaries of "covered drugs" dispensed through a qualifying Federal Agency Retail Pharmacy Program, collect and remit Industrial Funding Fees ("IFF") to V A, etc. Importantly, the transactions underlying the "refund" requirement are not procurements by a Big Four agency. Rather, the underlying transactions involve a retail pharmacy's purchase of a pharmaceutical product from a commercial source, followed by the sale of the product at a negotiated price to a beneficiary. Title passes from the commercial source to the retail pharmacy to the beneficiary; the Federal government never takes title or possession of the product. Federal dollars are introduced in the form ofre1mburscmcnts. Merck does not believe that the

retrospective introduction of federal dollars is sufficient to transfonn a commercial purchase into an authorized FSS order or creates a "virtual depot contracting system" to which Merck is a party.

A second defect with the Proposed Rule is that it appears to be outside GSA's statutory authority. Because V A is responsible for interpreting the VHCA, to the extent that the proposed rules involve substantive interpretation of the VHCA, V A (not GSA) should publish rules for notice and comment.

In addition, Merck believes that the Proposed Rule is ambiguous (which could cause significant operational difficulties) and imposes numerous additional record-keeping/reporting requirements. Ifthe Proposed Rule is not withdrawn, Merck respectfully requests that GSA clarify or reconsider several elements of the Proposed Rule, to include the following:

(1) Contract Modifications. The Proposed Rule is silent concerning the method by which the new clause would be incorporated into FSS contracts. FSS contracts include provisions stating that changes its tenns and conditions may be made changed only by written agreement of the parties. Merck requests GSA to clarify the Proposed Rule to reflect that modifications to current FSS contracts will require written agreement of the parties.

(2) Refund Calculations. Under the proposed clause, refunds would be calculated quarterly based on the difference between a benchmark price (either the actual sales price to the wholesaler or retail phannacy chain if known and auditable or the non-FAMP) and the FSS price or FCP, whichever is lower. However:

(a) The Proposed Rule does not specify whether the Federal agency or the contract holder would detennine the benchmark price to be used. Merck urges that this should be contract holder's decision, because the contract holder is in the best position to know the prices that it receives for its products from wholesalers or retail phannacy chains.

(b) The phrase "...if known and auditable..." is unclear as is the tenn "retail pharmacy chain." Merck respectfully requests clarification of these tenns.

(c) The Proposed Rule does not appear to address the importance of prospective identification of retail phannacies comprising the network phannacy. Such identification is essential so as to ensure that "refunds" are properly calculated (e.g., claims from ineligible phannacies, etc. are excluded).

(c) The proposed "refund" fonnula does not adjust potential differences between the package size (on which FCP is based) and the quantities of a covered drug that are considered in calculating the actual sales price (dispensed units, etc.).

(d) The Proposed Rule is unclear with regard to several aspects of non-F AMP calculations to include whether direct sales to retail phannacies may (or must) be included in non-F AMP calculations or whether utilization data may be handled in the non-FAMP calculation on a "cash" basis based on the date that a manufacturer pays a "refund."

(e) The Proposed Rule does not address the methodologies to be employed in situations where a product has been discontinued or when the patent covering a branded product has expired. With regard to the fonner, failure to synchronize multiple report dates could result in situations where the "refund" reporting period would extend beyond the period for which a non-F AMP was calculated.

(f) The Proposed Rule contemplates that a Federal agency administering a retail pharmacy program would provide utilization flat file layout reports to FSS contract holders on the 15th day of the first month after the close of a calendar quarter. The manufacturer would then have 70 days to calculate the "refund" amount owed, reconcile the calculation with the Federal agency calculation, and pay the "refund." Thus, the refund amount would be due 85 days after the close of each calendar quarter.

Additionally, the proposed clause would require FSS contract holders to report retail pharmacy sales and pay the IFF within 60 days of the close of the quarter. At a minimum, the schedules in the two clauses should be reconciled so that IFF payments are not due on retail pharmacy sales until the later of 70 days after the contract holder's receipt of full utilization flat file layout reports or 85 days after the end of each calendar quarter.

(g) Disputes. The Proposed Rule would require the contract holder to pay the refund according to the agency's calculation (including the disputed amount) and then use "best good faith efforts" to resolve the dispute within 60 days. This approach is inconsistent with the Contracts Dispute Act and with best business practices. Merck urges revision of the dispute resolution process to include a requirement for good faith negotiations coupled with a manufacturer's payment of only that portion of the "refund" that is not disputed and to pay any balance plus interest by the due date of the next quarterly payment after the dispute is resolved. In addition, Merck urges revision of the dispute resolution process to impose similar obligations on Government parties [e.g., requiring remittance of IFF payments (with interest) or remittance of overpayments (with interest) if good faith negotiations or a court decision subsequently result in a reimbursement of part of the refund to the contractor].

The Proposed Rule seems to suggest that (a) a manufacturer's costs, time and effort required to comply with the Proposed Rule is minimal; and (b) there are no alternative mechanisms whereby DoD could decrease its pharmaceutical costs in the retail pharmacy sector. Merck respectfully disagrees with both of these suggestions. The effort required to calculate and pay "refunds" is not "essentially clerical"; rather, evaluating and processing of thousands of transactions in compliance with multiple statutes requires significant advanced professional skills and additional computer capability and capacity. Further, the business practices of the private sector - which include the use of pharmacy benefits managers and expanded use of mail-order pharmacies - are two of many cost-effective alternatives that are readily available. It is noteworthy that a mail-order pharmacy is an existing component ofDoD TRICARE health system, the TRICAREMail Order Pharmacy ("TMOP"). For TRICARE beneficiaries, TMOP is a cost-effective alternative to the retail pharmacy: a beneficiary pays $3, $9 or $22 cost-share for a 30-dav supply of drugs in the retail pharmacy setting; in contrast, a beneficiary pays the same $3, $9 or $22 costshare for a 90-day supply of drugs for purchases made from the TMOP.

Merck appreciates your consideration of these comments. We remain committed to working with DoD, V A and others in the Federal government to develop alternatives that can accommodate the concerns raised by all parties in a manner that is consistent with existing laws. As we strongly believe that the Proposed Rule is not authorized under law and would have detrimental policy and implementation consequences, we urge its withdrawal.

Sincerely,

/SI

Senior Attorney

The Coalition for
Government
Procurement

1990 M Street, NW . Suite 400 . Washington, D.C. 20036. Phone (202) 331-0975. Fax (202) 822-9788 www.thecgp.org

June 9, 2005

Ms. Lauriann Duarte
FAR Secretariat
General Services Administration
1800 F Street, NW
Room 4035
Washington,D.C. 20405

RE: C;SAR Case 2005-GSOI

Dear Ms. Duarte:

The Coalition for Government Procurement is pleased to have this opportunity to submit comments on the above-referenced proposed rule issued in the April 12, 2005, *federal Register*. The Coalition strongly opposes the proposed rule.

The Coalition is a multi-industry association of government contractors. We have over 330 members representing all commercial item market segments. Our members account for over 70% of the sales made through the Multiple /\ ward Schedules program and about half of all commercial sales made annually to the federal government. Included in our membership is nearly every major pharmaceutical company selling through the V A Federal Supply Schedule program.

The Coalition has worked *'with* officials in government for over 25 y\:'ars for common sense acquisition rules. Specifically, we have worked with representative of GSA, the V A, 000, OMB, and Congress over the ability of the 000 Tricare TRRx retail pharmacy program to have access to federal ceiling prices on pharmaceuticals for nearly three years. This is the issue covered by the proposed rule. We believe this proposal put forth by GSA is an attempt to implement via regulation a scheme that the V A and DOD have not been able to implement otherwise.

INTERPRET A TION CONCERNS

We disagree that the proposed clause is consistent with Congressional intent under Section 603 of the Veterans Healthcare Act (VHCA) in the strongest possible terms. The Coalition has a long history of working with this statute

representmg commercial servIce and product suppliers to the Federal Government

and has had substantial opportunity to review the legislative history surrounding it. We believe strongly that this record shows that Congress did not intend to extend federal ceiling prices to pharmaceuticals the government, itself, never purchases.

The proposed rule covers pharmacy benefit plans of the "big four agencies" (V A, the Department of Defense. Public Ilealth Service and the Coast Guard) that are structured as follows: the agency contracts with a pharmacy benefit manufacturer to act as its fiduciary agent and use government funds to pay a share of it network retail pharmacies' charges for prescriptions ordered by the plan beneficiaries in accordance with a predetermined cost-sharing formula. The proposed rule would require inclusion of a special clause that would deem prescription orders of medication units places by beneficiaries with retail pharmacies to be orders of federal agencies from manufacturers under their FSS contracts. while eliminating the contractors' rights under FAR 52.216-18, 52. 216-19 See *552.238-XX.*

The rule mischaracterizes the transactions that occur at the pharmacy as "instructions to fill the prescriptions." The Pharmacy Benefit Manger (PBM) merely tells the pharmacy whether the beneficiary's federal plan will pay for it and how much. In fact, a prescription is an order from a physician to dispense drugs to a patient. and only the patient or a health care professiona'l can order a pharmacy to lill a prescription. The decision on whether to fill the prescription at all. whether to fill it as written. or whether to substitute an equivalent drug is that of the beneficiary, not the agency or its /iscal intermediary. The agency and the PBM can only control whether the government or the lx~ncliciary will pay f(Jr the prescription order and how much of the pharmacy charge will be shared.

In addition. the proposed rule ignores the fact that the retail pharmacy is the owner and source of the drug ordered and delivered to the beneficiary, and unlike procurements from the agency's prime vendor. there is no procurement contract with the retail pharmacy under which it promises to act as a conduit and sell goods to the government at the fSS price. In this construct, although the retail pharmacy receives the prescription order, fills it with product from its commercial stock, and is paid for it. it is not treated as the vendor from which FSS line items are sourced, but rather a "deemed" purchasing agent of the government.

The Coalition is concerned with this line of reasoning implicitly taken by GSA in the proposed rule. The pharmacy does not purchase the dispensed units ordered by the beneficiaries from manufacturers under the FSS contracts pursuant to a contract with the agency. It buys drugs from commercial sources. takes title. and uses them in its business, charging a negotiated price for dispensed units unrelated to the FSS contract price. Were it truly a purchasing agent, it would be contractually required to pass on the FSS contract price. Nor is the pharmacy a cost "subcontractor" entitled to buy o/Tthe FSS undcr existing FAR rules because it is not paid its acquisition cost plus a fixed fee for drugs used by the prime in performance of a government contract and is not subject to procurement rules applicable to cost contracts. A specific statute is necessary to mandate these particular FSS contractors pretend retail pharmacy sales of

medications they manufacture are indirectly ordered from them on behalf of particular government agencies. Even the prime vendor program requires manufacturer consent.

The proposed rule forces certain FSS contractors, manufacturers of covered drugs, to agree as a condition of selling their products on the Federal Supply Schedule to the following contract term: approval by a fiscal intermediary of select agencies to pay one of its network health care providers a share of the provider's charge for an order placed by an agency program beneficiary shall be "deemed" an order by the agency from the manufacturer "through" the provider under the FSS contract, thereby granting the agency a contractual right to the contract price from the manufacturer on these third party payment transactions. Imposing these legal obligations on certain FSS contractors through the terms of their FSS contracts is unprecedented and unauthorized by any statute.

The Coalition also feels that the proposed rule is not clear in the statutory source of authority for granting the big four agencies the special contract rights contemplated, i.e., whether GSA's own statutes or the VHCA authorizes GSA to amend the GSAR in this manner. It is our belief that the applicable rules and statutes do not provide this authority. We are particularly concerned that the scope of the proposed rule is not limited to statutory ceiling prices available to the big four, but would require VA FSS contractors to extend their negotiated prices to particular federal program beneficiaries.

The Master Agreement and the pricing agreement required by the VHCA provide that actual contract prices are to be negotiated in good faith within the prescribed framework of the FAR, GSAR. V A acquisition regulations and other applicable rules. The FCP is merely a cap on those prices for the four agencies that procure pharmaceuticals for use in providing treatment at their facilities. The Coalition does not believe that GSA has the statutory authority to change the GSAR to grant select agencies special contract rights with respect to certain products of certain contractors under FSS contract rules and to read out rights to order limitations provided by the FAR. We know of no law that would permit GSA to "deem" the j()llowing: an order placed by a beneficiary is an order placed by an agency; an order placed with a retailer is an order placed with the contractor, and an order placed for medication units that are not described in the contract CLIN structure is an order of product units ofrcred for sale bv manufacturers under the contract.

We also believe that there is no authority to alter the bargain struck with respect to the negotiated terms of the conlract. When manufacturers of covered drugs offer sub-ceiling prices under the FSS, the contracts arc treated the same as all other FSS contracts for goods. Clearly, the VHCA does not deal with virtual depot contracting systems because, prior to the current effort to expand the original intention of the Act. there was no such concept. There is nothing in the VHCA that compels manufacturers to extend rss prices to depot contracting systems.

An additional Coalition concern is that the proposed rule, itself, is inconsistent with GSA's own precedent setting determinations on schedule eligibility. The agency has previously, and

G501-9

consistently, rejected eligibility claims made on criteria to those substantially the same as those now put forth in the proposed rule. We believe strongly that the transactions between beneficiaries and retail pharmacies are not procurements. Rather, they are more closely identified as an agency or other entity receiving federal funds under a Cooperative Agreement, grant, loan, or other sub~idy.

GSA has repeatedly rejected the interpretation that such transactions are procurements because the government can only use a procurement contract to pay for goods that are acquired for its own use. There is no procurement here. The transactions are payments by a fiscal intennediary reimbursing a retail pharmacy a cost share for providing a prescription to a beneficiary and have the same purpose as if the fiscal intermediary reimbursed the beneficiary who received the prescription the same amount if he or she paid the whole charge.

The Coalition believes that the nature of the transaction is that ofa subsidy or insurance payment, \\'hich the FAR recognizes as a non-procurement transaction. See FAR 9.403. This distinction is similar to the difference between a voucher to obtain goods or services in the private sector and a procurement. *i*\ pharmacy dispensing a prescription to a Tricare beneficiary paid in part by DOD is no more ordering drugs for the Government than a landlord is leasing to the Government when HUD pays it a rental subsidy. or a retail grocer is ordering food for the Government when it accepts food stamps redeemed by DOA. or a private school is educating the Government when it accepts a tuition voucher from the student. In each of these cases the Government can choose to meet the health care. housing, educational or nutritional needs of its beneficiaries by directly providing them, in which case it can procure goods it needs to function as a provider (e .g., build and rent out low cost housing or buy and distrihute

Case lav\ supports an interpn:tation of the Tricare system as an assistance program rather than a procurement contract. For example. in *Partridge v. Reich,* a county fire department recei\.ing federal funds under a contract between the Federal Emergency Management Agency C'FEMA") and the State allegedly violated the Veterans Readjustment Assistance Act ("VEVRA"), which required procuremcnt contractors to implement affirmative action plans for veterans. The court determined that VEVRA did not apply to all agreements between the Federal government and third parties. but only to contracts for "procurement" for personal prQperty and services for lIse by the government. concluding that an agreement to pay for emergency service between FEMA and the State was not a contract for "procurement" of services by FEMA. Likewise, the statutes authorizing GSA to execute procurement contracts with manufacturers do not extend to expenditures of federal funds for their products under non-procurement agreements.

In this case, DOD is making financial assistance payments to civilian pharmacies for prescriptions acquired not by DOD-which does not have a legal right to the dispensed drugs but by Tricare beneficiaries. There is no direct use by or for the Government, as required by the FAR. Accordingly, reimbursement of prescription claims is not a procurement of drugs by 000.

By implementation of the Uniform Formulary multi-tiered structure in April 2004, the DaD moved toward creating a situation where pharmaceutical manufacturers were competitively incentivized to offer the agency more favorable pricing to achieve optimal formulary status. Thi";~ "onsistent with the best practices commercial model and the intent of the Congress. By the government setting prices through this proposed rule and a rebate mechanism it has effectively removed the market incentives to control costs. The Coalition feels that this is not in the government's best long-term interest.

On a final point in this area. the Coalition wishes to point out that throughout the government's attempts to expand the authority of the YHCA to include TRICARE retail pharmaceutical sales, the terms *"rebate"* and *"di.scOlmt"* have been used interchangeably as if they were synonymous. This is not the case. A *"discount"* is an upfront reduction in purchase price nonnally based on favorable trade terms or preferred customer status. The Federal Ceiling Price described in the section 603 of the YHCA is a *"discounted"* price. A *"rebate,"* however, is a backend return of a proportion of the original purchase price usually based on volume of sales. The YHCA does not authorize or discuss *"rebates."* However. *"rebates"* are what are being proposed by this GSA rule.

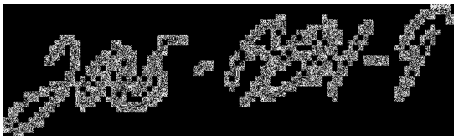
OPENING THE SCHEDULE TO BENEFICIARIES

lhe proposed rule deems orders of supplies by federal beneficiaries placed with retailers for the personal use of the beneficiaries to be orders from the schedule contractors. Yet. neither beneficiaries nor retailers arc authorized users of the schedule contracts. By authorizing indirect use through "deemed orders." the proposed rule authorizes use by entities that could not place orders directly. The Cl1alition does not believe that the YHCA authorizes this scheme. Similarly, we do not believe that the laws and regulations governing the Multiple Award Schedules program allow for these types of pmcuremcnts. As such. the Coalition believes that the proposed rule is fundamentally incompatible with the intent of the schedules program. Taken to its next step, GSA could just as easily open up the MAS program to deemed orders by grantees, loan recipients, or others
mtitlcd to have federal agency funds pay for goods.

We see this as a very dangerous precedent that would undoubtedly have a substantial and deleterious impact on the government's largest commercial item procurement method. The ramifications of this potential are huge. We strongly recommend steering away from this course as the agency reconfigures itself and continues to respond to criticism that some customers already make improper use of GSA contracts.

IMPACT ONOFPP ACT

The Office of Fcderal Procurement Policy Act (OFPP A) incorporates the Chiles Act, 31 U.S.C.6303-6305, which prohibits agencies from using procurement contracts for transactions when the purpose is the acquisition of supplies for the benefit and use of parties other than the Government. That is why we have grants. cooperative agreements. assistance agreements, and other transactions. Here, the drugs arc not entirely paid for by the agency and they are not being used by the agency. It is contrary to law and federal procurement policy to Jllow GSA to use the FSS to cover assistance trans:lctions.



IMPLEMENTATION CONCERNS

Aside from the fact that there is no statutory authority for this proposal, the Coalition is also very concerned over the manner in which GSA would implement the proposed regulatory change, even if some heretofore unknown authority does exist, on established contracts already in existence. Certainly the change contemplated by the proposed rule greatly alters cUlTent contracts. Even if GSA has the discretion to insert ncw clauses in new contracts and solicitations, without clear statutory authority to impose such new obligations on the contractors during the base term, the proposed rule's clause will be a cardinal change. We see no alternative other than negotiating brand new contracts based on this new reality with every pharmaceutical contractor and ending all cUlTent contracts. This would be a very substantial undel1aking as the contracts cUlTently in place took several years to negotiate and award.

We see this as a substantial burden to contractors, especially small businesses. It does not seem that

this impact was adequately assessed in the *Federal Register* notice. We request that an appropriate

small business impact statement be prepared before any formal rule goes forward and that the comment period be extended to allow small firms adequate opportunity to comment on the resultant findings.

CONCLUSION

The Coalition believes that the proposed rule is not in the best interest of government, industry, or Tricarc bencliciaries. We believe it is csscntially a political attempt to provide coverage for a program badly v,anted by DOD to meet now-expected budget parameters, but which fails to pass regulatory or

statutory muster. It simply does not provide adequate, or in our view legitimate, legal justification to achicve the desired cnd. We urge the withdrawal of the rule and recommend that 000 and the V A seek other means to achieve their end in cooperation with their industry partners.

Sincerely,

LaITV Allen
Executive Vice President

June 13, 2005

BY HAND DELIVERY

Ms. Laurieann Duarte
General Services Administration
Regulatory Secretariat (VIR)
1800 F Street, N.W., Room 4035
Washington, D.C. 20405

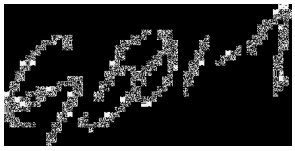
Re: GSAR Case No. 2005-G501

Dear Ms. Duarte:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to comment on the Proposed Rule published by the General Services Administration ("GSA") on April 12, 2005.1 PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA recognizes the extraordinary sacrifices made by the men and women of our military and is committed to doing its part to assure that they have access to the best possible medicines and the highest quality health care. We offer these comments because we do not believe the Proposed Rule is the best way to achieve our mutual objective of making available the best quality care to our military personnel and their dependents. Additionally, we believe that the underpinnings of the Proposed Rule are not sound.

The Proposed Rule would establish a supplemental General Services Administration Regulation ("GSAR") clause, entitled "Federal Agency Retail Pharmacy Program Supply Schedule," that could be incorporated into the Federal Supply Classification ("FSC") Group 65 Federal Supply Schedule ("FSS") contracts. This new clause would permit the Department of Defense ("DoD"), the Department of Veterans Affairs ("V A"), the Coast Guard, and the Public Health Service ("PHS") (collectively, "the Big Four") to obtain rebates, referred to in the Proposed Rule as "refunds," from FSS contractors on sales of "covered drugs" dispensed through a qualifying "Federal Agency Retail Pharmacy Program." The clause also would require FSS contract holders to report qualifying retail pharmacy sales to the V A and allow the V A to collect an Industrial Funding Fee ("IFF") on those sales. The clause would not affect the amount

1 70 Fed. Reg. 19.045 (Apr. 12, 2005).



that beneficiaries of the TRICARE health system (or any other health system) would pay for their prescriptions? Nor would it increase, improve, or affect beneficiary access to medicines.

The Proposed Rule should be withdrawn for two general reasons:

(1) The GSA lacks statutory authority to implement the Proposed Rule; and

(2) The Proposed Rule would create significant operational problems for both the V A and FSS contract holders.

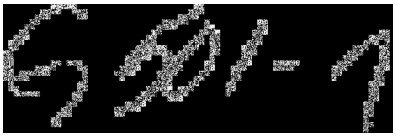
The most effective means to meet the budget objectives cited as the basis for the Proposed Rule is the competitive marketplace, not the extension of price controls or other artificial price constraints or price ceilings as the Proposed Rule contemplates.3 The commercial sector employs several types of market-based approaches, including competitive negotiations.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), passed by Congress and signed into law by President Bush on December 8, 2003, establishes a market-based approach for managing the new prescription drug benefit for the more than 40 million Americans who are enrolled in the Medicare program.4 In our view, a similar market-based solution would work well for the DoD and the V A in their efforts to develop a retail pharmacy benefit, where the government's role is as a third-party payer as opposed to a direct provider of the prescription drugs that are dispensed to its beneficiaries. And, unlike with the approach set forth in the Proposed

2 The cost shares paid by TRICARE beneficiaries are defined in a Uniform Formulary Rule issued on April 1,2004. *See* 69 Fed. Reg. 17,035 (Apr. 1,2004).

3 Indeed, prior government reports have suggested that making FSS pricing available to the private sector would have unintended adverse consequences for the prices for other health benefit plans. *See, e.g.*, Gen. Accounting Off., Pub. No. GAO/HEHS-00-118, Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes (Aug. 7, 2000).

4 Among other provisions, the MMA requires that there must be at least two approved prescription drug plans per Medicare region from which beneficiaries may choose and that each drug formulary must contain :1t 1east two drugs per therapeutic do"'... MMA, Pub. L. No.] 08-173, II? Stot. ~066 (2003).



Rule, we are not aware of any statutory or regulatory impediments to the development of market-based approaches to cost containment by either the DoD or the V A. 5

For the reasons stated in this letter, the GSA should withdraw the Proposed Rule and encourage the DoD, the V A, and other Federal agencies to pursue market-based solutions as alternatives to the "refund" process that the Proposed Rule contemplates.

I. The Proposed Rule Is Not Authorized by Law

A. The GSA is Not Authorized to Promulgate the Proposed Rule

The principal defect with the Proposed Rule is that it is outside of the GSA's statutory authority. Accordingly, we believe that the GSA's promulgation of the rule would be an ultra vires agency action. It also would be fundamentally at odds with one of the five major objectives of the GSA's "Get it Right" plan to: "ensure compliance with federal acquisition policies, regulations and procedures.,,6

The preamble to the Proposed Rule does not specify the statute or statutes under which the rule would be issued or explain how the Proposed Rule itself would be consistent with Congressional intent. However, the preamble and the rule reference three statutes that the GSA apparently believes support parts or all of the Proposed Rule: (1) Section 603 of the Veterans Health Care Act of 1992 ("VHCA"), 38 *V.S.C.* § 8126; (2) Sections 201(a) and 309 of the Federal Property and Administrative Services Act ("FPASA"), 40 *V.S.C.* § 501 and 41 *V.S.C.* § 259(b); and (3) the National Defense Authorization Acts of 1999 and 2000, 10 *V.S.C.* § 10 74g. None of these statutes contemplates the rule under consideration.

5 As explained in section LA.3 below, use of a market-based solution would be consistent with the Congressional requirement that DoD adopt "the best business practices of the private sector" in establishing an integrated and uniform health benefit for its beneficiaries. *See* 10 *V.S.C.* § 1074g(a) (2004).

6 See Gen. Servs. Admin., Get It Right: A Comprehensive, Governmentwide Approach at 7, *available at* http://www.gsa.gov/gsalcm _ attachments/GSA _ DOCUMENT/GIRight%20 _ org-pre-R2 _ iF 1 B _ OZ5RDZi34K-pR.ppt/269.

1. The Veterans Health Care Act of 1992,38 V.S.C. § 8126

Summary of the VHCA. In relevant part, the VHCA requires manufacturers of "covered drugs" to enter into Master Agreements and Pharmaceutical Pricing Agreements ("PP As") 7 with the V A under which manufacturers agree to make a statutorily-mandated discount, known as the Federal Ceiling Price ("FCP"), available to the Big Four agencies for all of the manufacturer's covered drugs that are "furchased under depot contracting sys~ems or listed on the Federal Supply Schedule." The VHCA defines the term "depot" as:

> a centralized commodity management system through which covered drugs procured by an agency of the Federal Government are
>
> (A) received, stored, and delivered through
>
> (i) a federally owned and operated warehouse system, or
>
> (ii) a commercial entity operating under contract with such agency; or
>
> (B) delivered directly from the commercial source to the entity using such covered drugs.9

The Proposed Rule concludes that a Federal Agency Retail Pharmacy Program would qualify for Federal pricing because it would constitute a "virtual" depot contracting system, but does not articulate the statutory basis for this conclusion.lo Indeed, as described below, this conclusion lacks statutory support.

7 If a manufacturer does not have an executed Master Agreement and PP A, then it may not receive payment for purchases under Medicaid and other programs. *See* 38 *V.S.C.* § 8l26(a)(4).

8 *!d.* § 8l26(a)(2). 9

Id. § 8 I 26(h)(3).

10 70 Fed. Reg. at 19,050 (Subsection (c)(2) of the proposed clause notes that a Federal Agency Retail Pharmacy Program is a "virtual depot system").

The VHCA Is Narrow in Scope. Congress intended for the VHCA to have a limited application. Both the Senate and the House Committee Reports relating to the VHCA recognized the four means by which the V A and DoD procured drugs (FSS contracts, a depot system, a single award contract and open market purchases) II and extended the FCP to procurements made through only the first two of those methods. Congress did not reference DoD reimbursement for drugs dispensed under the CHAMPUS program (the TRICARE predecessor civilian health insurance program), thus demonstrating Congress' intent that the FCP should not apply to government reimbursement programs, such as a retail pharmacy program. 12

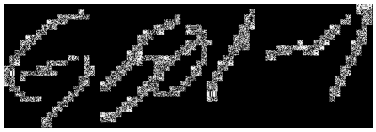
The V A has previously construed the VHCA consistent with Congress' intent. Until recently, the V A defined the term "depot" to include only "centralized commodity management systems through which covered drugs are: (A) received, stored and delivered to a listed federal agency through a federally-owned warehouse system or a commercial warehouse system operating under contract with the procuring federal agency; or (B) delivered directly from the manufacturer or its agent to a listed federal agency's ordering activity at its purchasing address.,,13 Neither of the definitions that the V A previously used would encompass a Federal Agency Retail Pharmacy Program where there is no procurement contract between the drug manufacturer and the government or the government's purchasing agent. Furthermore, the VA expressly concluded in 1994 that the VHCA "does not require manufacturers to grant the discount to . . . government contractors authorized to use the FSS" and specifically characterized the VHCA as imposing a "limited" discount. 14 These statements are directly at odds with the

II S. Rep. No. 102-401, at 62-63 (1992); H.R. Rep. No. 102-384 (I), at 4 (1991).

12 In promulgating the VHCA, Congress understood the important distinction between the government as a third party payer and the government as a direct purchaser of drugs, and understood that the latter could result in a depot contracting system whereas the former could not. *See* S. Rep. 102-228(1), DEVELOPMENTS IN AGING: 1990-VOLUME 1, 1991 WL 52579 at *254 (Mar. 22,1991) (recognizing that depot prices are excluded from best price calculation under the Medicaid Rebate statute because "depot prices reflect the manufacturer's costs of delivering the product in bulk to a provider, without packaging costs" and that, because "Medicaid is a reimbursement system, not a direct purchaser of drugs," it would be "unfair for Medicaid to have access to prices that are determined based on this mode of distribution. ").

13 Letter from Phillipa L. Anderson, Assistant General Counsel, Dep't of Veterans Affairs, to Robert D. Seaman, General Counsel ofTRICARE Management Activity (Nov. 1,2001). (Attached as Exhibit A).

14 Letter from William E. Thomas, Jr., Assistant General Counsel, Dep't of Veterans Affairs, to Lt. Col. Henry L. Smith, OASD (HA) HSF/MCO, the Pentagon 1 (July 28, 1994). (Attached as Exhibit B).



unprecedented interpretation of "depot" that underlies the Proposed Rule's conclusion that a retail phannacy program qualifies as a depot contracting system.IS

The DoD has also previously recognized that the VHCA does not authorize agencies to apply the FCP to retail phannacy sales. Following a 1996 VA letter to covered drug manufacturers rejecting a DoD request to apply the VHCA to TRICARE network retail phannacies, the DoD expressly sought legislation "to specifically bring the procurement of phannaceuticals on behalf of DoD by an authorized contractor through an authorized retail phannacy or mail order program within the purview of38 *V.S.C.* § 8126.,,16 Congress did not change the law in response to the DoD's request. The DoD's decision to seek such legislation confirms the DoD's understanding that the VHCA did not then, and therefore does not now, extend to retail phannacy sales.17

The Proposed Rule Conflicts with the VHCA Definition of "Depot. "
Notwithstanding Congress' intent that the VHCA apply only to Federal procurements of covered drugs and the V A and DoD's prior interpretation of the VHCA, the preamble to the Proposed Rule concludes that: "[t]his rulemaking is consistent with the authority provided by 38 *V.S.C.* § 8126 to acquire drurs at the statutorily provided discount through use of a depot contracting system.,,1 PhRMA respectfully disagrees. As the VA previously concluded, the term "depot" in the VHCA does not extend to retail phannacy programs and does not apply to "virtual" depot contracting systems. The definition of "depot" in the VHCA specifically requires a "centralized commodity management system" through which covered drugs are "procured" by an agency of the Federal government. The term "procurement" has a well-established meaning: it refers to the

151n October 2004, the V A announced to covered drug manufacturers that DoD's TRICARE Retail Pharmacy ("TRRx") Program complied with the VHCA because the retail pharmacy benefit as structured was a "virtual" depot contracting system. Letter from Steven Thomas, Acting Executive Director, VA National Acquisition Center, to Manufacturer of Covered Drugs (Oct. 14,2004). (Attached as Exhibit C). However, the V A did not explain the basis for this conclusion or explain why its interpretation of the VHCA changed.

16 White Paper for the Office of the Secretary: TRlCARE and Federal Ceiling Prices at 4 (Oct. 10,2002). (Attached as Exhibit D).

17/d.

18 70 Fed. Reg. at 19.046

acquisition of goods and services with appropriated funds for the government's benefit or use.19

The drugs that would be dispensed through a Federal Agency Retail Pharmacy Program are not "procured" by a Federal agency. Instead, the retail pharmacy would procure the drugs through its contracts with commercial wholesalers or manufacturers, and the program beneficiary in turn would procure the drugs from the retail pharmacy. The Federal government would never take title to or possession of the drugs. There would be no procurement contract under which drug manufacturers agree to provide the covered drugs in question to the Federal government or a vendor or agent of the Federal government. 20 Nor would there be any contract under which manufacturers agree to make the FSS (or FCP) available for the drugs that are dispensed through retail pharmacy programs. The government's sole role in the retail pharmacy transaction would be to authorize the pharmacy to fill the prescription and to reimburse the pharmacy (after the fact) for the government's share of the retail price.21 Because there would be no Federal procurement of the drugs that are involved in this transaction, a Federal Agency Retail Pharmacy Program would not qualify as a depot contracting system under the VHCA.

The Proposed Rule Does Not Explain Why a Federal Agency Retail Pharmacy Program Would Qualify as a Depot Contracting System. As noted, contrary to prior determinations, the Proposed Rule concludes without explanation that the Federal Agency Retail Pharmacy Program r:rocedures established in the proposed clause "are consistent with 38 *V.S.C.* § 8126." 2 The GSA must specify the basis for this

19 See 41 D.S.C. § 403 (2003); 48 C.F.R. § 2.101 (2005). *See also Appeal of Mayer,* HUDBCA No. 83-823-C20, 84-2 BCA 1 17,494 (1984) ("acquisition by purchase, lease, or barter, of property [or] services *for the direct benefit or use* of the Federal Government... characterizes a Federal procurement.") (emphasis added).

20 Retail pharmacies are not prime vendors or purchasing agents of the Federal government.

21 Both the Federal Acquisition Regulations ("FAR") and the V A rules include insurance transactions and subsidies, such as a Federal Agency Retail Pharmacy Program, within the defmition of "non procurement transactions." FAR § 9.403 (2005); 38 C.F.R. § 44.970 (2005).

2270 Fed, Reg. :It 19.050.

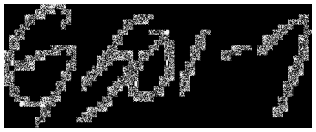
conclusion.23 In particular, the GSA does not specify the part of the VHCA definition of "depot" that authorizes a Federal Agency Retail Pharmacy Program. If the GSA believes that the second alternative definition of depot *(i.e.,* direct delivery of the covered drugs from a commercial source to the entity using the covered drugs) supports this conclusion, then, at a minimum, the GSA must identify the entities that it believes constitute the commercial source and the end user ofthe covered drugs that would pass through the Federal Agency Retail Pharmacy Program.

Likewise, the Proposed Rule does not specify the contractual basis for its apparent conclusion that a Federal Agency Retail Pharmacy Program involves a Federal procurement. For example, the Proposed Rule does not identify any procurement contract under which a manufacturer agrees to sell the covered drugs that would be dispensed through the retail pharmacy program to a Federal agency or an authorized purchasing agent for the Federal price. Nor does the Proposed Rule identify a contract between a Federal agency (or its pharmacy benefit manager) and the retail pharmacies under which the retail pharmacies agree to act as a purchasing agent or prime vendor for the Federal agency. Such contracts would be prerequisites to a Federal procurement, which in turn is a prerequisite to a depot contracting system under the VHCA. PhRMA respectfully requests a full explanation of the basis for the Proposed Rule's conclusion that a Federal Agency Retail Pharmacy Program, if compliant with the procedures set forth in the proposed clause, would qualify as a depot under the VHCA.

The GSA Lacks Authority To Interpret the VHCA. The GSA, and not the V A, issued the Proposed Rule that purports to interpret the VHCA. While the V A did issue a letter to covered drug manufacturers in October 2004 that ostensibly authorized the DoD's TRICARE Retail Pharmacy Benefit ("TRRx") Program, that letter was not published for notice and comment. 24 Moreover, the V A, and not the GSA, is responsible

23 PG&E Transmission, Northwest Corp. v. *Fed. Energy Regulatory Comm.,* 315 F.3d 383,386 (D.C. Cir. 2003) (Agency must be able to demonstrate that it has made a reasoned decision based upon substantial evidence in the record and articulate a satisfactory explanation for its actions including a rational connection between the facts found and the choice made.).

245 U.S.C § 553.



for interpreting the VHCA.25 The V A, and not the GSA, should publish rules for notice and comment to the extent that those rules are premised on a substantive interpretation of the VHCA. The GSA interpretations ofthe VHCA are not entitled to legal deference.

The VHCA Does Not Authorize Federal Agencies To Obtain FSS Pricing. Independent of the Master Agreement and PPA mandated by the VHCA, manufacturers and the V A also establish FSS prices for drugs sold under the FSS contracts. FSS prices are developed pursuant to the terms and conditions of the FSS contract solicitations.26 As the Proposed Rule acknowledges, the FSS price for a drug can be lower than the drug's FCp?7 The VHCA does not authorize Federal agencies to access FSS prices for their depot contracts. Nor does the VHCA permit Federal agencies to collect rebates from manufacturers. Instead, as noted, the VHCA only allows the Big Four agencies to acquire covered drugs through a depot contracting system at a statutorily-mandated discounted price that is no higher than the FCP (not the FSS). To the extent that the VHCA is cited as support for the payment of rebates designed to approximate FSS pricing, the clause would thus be invalid. The GSA should clarify that it is not relying on the VHCA for its proposal to require payment of rebates based on the FSS prices for retail pharmacy purchases.

2. The Federal Property and Administrative Services Act ("FPASA"), 40 V.S.C. & 501 and 41 V.S.C. & 259(b)

Summary of FP ASA. The preamble to the Proposed Rule also cites two sections of the FP AS A, apparently as support for part or all of the rule and the proposed supplemental GSAR clause. The first cited provision, Section 201(a) of FPASA, authorizes the GSA to "procure and supply personal property and nonpersonal services for executive agencies to use in the proper discharge of their responsibilities.,,28 The

25 See TRICARE, Federal Pricing Forum Questions (answering questions raised at the May 11, 2004 Industry Conference re: TRRx), *ovai/llble al* http://www.tricarc.osd.millpharm_ mfg/downJoadsiFederalPricingForumQucsAns _ Final.pdf (posted Oct. 28, 2004) ("GSA does not have jurisdiction over TRICARE or the application of Federal ceiling prices to TRRx under [the VHCA]").

26 Price Reductions (May 2004), 48 C.F.R. 552.238-75. 2770

Fed. Reg. at 19,050.

2840 U.S.c. § 501 (b){\ )(A).

second cited provision, Section 309, is a FP ASA definitional section that includes procedures established by the GSA for the award of multiple award schedule contracts (such as FSS contracts) within the definition of "competitive procedures" if: (1) participation in the multiple award program is "open to all responsible sources"; and (2) contracts awarded through the GSA ~rocedures result in "the lowest cost alternative to meet the needs of the government.,,2 Thus, Section 309 provides that "competitive procedures" are those procedures under which an "executive agency" enters into a contract pursuant to full and open competition, and that the term "competitive procedures" can include those procedures adopted by the GSA relating to the award of multiple award schedule contracts.

Congressional Purpose of FP ASA. The purpose of FP ASA is to empower the GSA "to provide the Federal Government with an economical and efficient system for. . . procuring and supplying property and nonpersonal services.,,3o Congress authorized the GSA "to regulate the policies and methods of executive agencies with respect to the procurement and supply of personal property and nonpersonal services.,,3 For purposes of FP ASA, the term "procurement" means "all stages of the process of acquiring property or services, beginning with the process for determining a need for property or services and ending with contract completion and closeout.,,32

FPASA Does Not Authorize the Proposed Rule. Neither of the two FPASA provisions cited by the GSA (nor any other FP ASA provision) authorizes the Proposed Rule. As noted, FP ASA permits the GSA to establish procedures that govern the procurement of property and services for use by executive agencies. For the reasons described in the discussion of the VHCA above, the retail pharmacy program authorized by the Proposed Rule does not involve Federal procurement of the covered drugs that would pass through the retail pharmacy program. Accordingly, the cited FP ASA provisions do not apply.

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2941 U.S.c. § 259(b).

3040 U.S.c. § 10l.

31 H.R. Rep. No. 670, 81st Cong., 1st Sess. (1949), *reprinted in* 1949 U.S. Code Congo & Admin. News
1475.

3241 1 J,S.C. § 403.

Moreover, FP ASA does not contemplate the establishment of procedures, such as those in the Proposed Rule, under which a Federal agency's instruction to a retail pharmacy to use its commercial inventory to fill a prescription for an agency beneficiary could be deemed an order under an FSS contract of the drugs used to fill the prescription. As described in section B below, an order must be placed "directly with the contractor in accordance with the terms and conditions of the pricelists.,,33 Deemed orders do not meet this requirement. In short, there is no nexus between FPASA and the Proposed Rule's provision that an instruction from a Federal agency to a retail pharmacy can substitute for an authorized entity's order under an FSS contract. 34

The GSA's Prior Interpretations of FPASA Do Not Permit Agency Instructions to be "Deemed" Orders under FSS Contracts. The GSA has issued an order (the "GSA Order") that identifies the entities and organizations that are eligible to order supplies and services from FSS contracts.35 The GSA Order confirms that FSS contracts can be used to "procure and supply personal property and non-personal services for executive agencies and other Federal agencies, mixed-ownership Government corporations as identified in the Government Corporation Control Act, the District of Columbia, and qualified nonprofit agencies for the blind or other severely handicapped for use in making or providing an approved commodity or service to the Government.,,36 The GSA Order also explains that other organizations may be eligible to order from the FSS pursuant to other sections of FP ASA or "by reason of enabling statutory authority.'.J7

33 FAR § 8.406-1.

34 *See Liberty Mut. Ins. Co. v. Friedman,* 639 F .2d 164 (4th Cir. 1981) (citing *Chrysler Corp. v. Brown, 441*
U.S. 281, 308 (1979)) (To establish that a regulation is promulgated pursuant to power conferred by Congress, there must be a "nexus between the regulation[] and some delegation of the requisite legislative authority by Congress.").

35 GSA Order ADM 4800.2E (Jan. 3, 2000) ("GSA Order").

36 GSA Order at 1

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37 GSA Order at 1 3; *accord, id.* at 1 7 ("Organizations are eligible to use GSA sources of supply and services pursuant to the Property Act or other statutory authority"). The Scope of Contract clause in the FSS contracts recognizes a further potential limitation: an FSS contractor is not obligated to accept orders that are not "received from activities within the Executive Branch of the Federal Government." *See* I-FSS 103 Scope of Contract - Worldwide (July 2002). Thus, although approved cost reimbursement contractors can order from the FSS, the FSS contractor is not required to accept orders from those cost reimbursement conlmclon;.

The GSA Order confinns that authority under a statute or a properly issued regulation - *i.e.,* a regulation that is within the scope of existing statutes and that does not conflict with acquisition regulations - is required before a new entity can be granted access to the FSS. As discussed above, the drugs dispensed through a Federal Agency Retail Phannacy Program would be purchased by an agency beneficiary and filled from the retail phannacy's commercial inventory. The drugs would not be ordered by an executive agency under an FSS contract. The Proposed Rule is thus not consistent with the GSA Order. Moreover, the expansive concept of a "deemed" order (in lieu of an actual order) that underlies the Proposed Rule could set adangerous precedent that could apply to FSS contracts for other products, and thereby result in a slippery slope that could undennine the integrity and upset the economics ofthe GSA FSS contracting system. For these reasons, implementation of the Proposed Rule would violate FPASA and would exceed the GSA' s authority.

3. National Defense Authorization Acts of 1999 and 2000, 10 D.S.C. & 1074g

Citing the National Defense Authorization Acts of 1999 and 2000, the preamble to the Proposed Rule also suggests that the Proposed Rule is "required by DoD in order to reengineer its TRICARE Phannacy Benefits Program.,,38 The cited authorization statutes directed the DoD to "establish an effective, efficient, integrated phannacy benefits program" and to incorporate "the best business practices of the private sector" in implementing the program redesign.39

No provision in either of these authorization statutes would allow the GSA to extend the scope ofFSS contracts in the unprecedented manner proposed in the rule. Rather, these statutes required the DoD to develop a unifonn fonnulary through which its beneficiaries would be able to receive a unifonn and integrated health benefit throughout the three points of service in the TRICARE health system: Military Treatment Facilities ("MTFs"), the TRICAREMail Order Phannacy ("TMOP"), and retail phannacies. The DoD promulgated regulations implementing these statutory requirements in April 2004.40

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38 70 Fed. Reg. at 19,046.

39 10 V.S.C. § 1074g(a). This statute applies only to the 000. It would not have any bearing on a retail pharmacy benefit offered by the V A, the PHS or the Coast Guard.

4069 Fed. Reg 17,035 (Apr, 1,2004),

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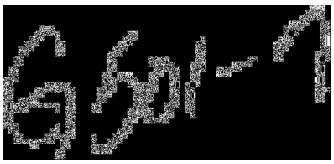

Under those regulations, TRICARE beneficiaries who purchase their drugs in network retail pharmacies are required to pay $3 for a 30-day supply of generic drugs; $9 for a 30-day supply of drugs that the DoD Pharmacy and Therapeutics ("P&T") Committee detennines to meet its standards of clinical and cost effectiveness; and $22 for a 30-day supply of drugs that the P&TCommittee detennines not to meet its standards of clinical and cost effectiveness. For those same cost shares, a TRICARE beneficiary can obtain a 90-day supply of the same prescription drugs through the TMOP. TRICARE beneficiaries do not pay a cost share for drugs obtained in MTFs.

The Proposed Rule would not affect these beneficiary cost share requirements or increase beneficiary access to prescription drugs. It would, however, reduce the DoD's costs for covered drugs that are dispensed in network retail pharmacies. Thus, finalization of the Proposed Rule could incentivize the DoD to promote utilization of the retail pharmacy point of service, where the DoD has set higher beneficiary cost-sharing amounts. Contrary to helping beneficiaries to obtain affordable medicines, the Proposed Rule could have the opposite effect.

We also do not believe that expansion ofFSS contract pricing in the manner suggested in the Proposed Rule would be consistent with the "best business practices of the private sector." Rather, expansion ofthe FSS contracts to commercial sales in the manner suggested in the Proposed Rule would directly conflict with private sector practices. Federal pricing, including the Price Reductions clause in the FSS contracts and the price ceiling mandated by the VHCA, does not apply in the private sector and is not a commercial business practice.

The business practices of the private sector do include a number of models that are available to the DoD (and other Federal agencies) that could be used to help contain drug acquisition costs. For example, it is commonplace in the private sector for purchasers or their agents to negotiate rebate agreements with manufacturers and use a variety oftools to achieve cost savings.41 Such a system could work well within the DoD and would be consistent with what Congress intended when it directed the DoD to

41 The DoD's PBM apparently is prohibited by contract from negotiating or collecting rebates of any type from pharmaceutical manufacturers. Contract MDA 906-03-C-0019 at 5 (Sept. 26, 2003). This contract provision may be inconsistent with the statutory requirement that the DoD incorporate "the best business prncticcs ofthe private sectnr" into it!! TRICARE heahhcnre lIystcm.

incorporate the best business practices of the private sector into its TRICARE health system. 42

B. The Proposed Rule Is Inconsistent with the FAR

The "deemed order" requirement of the proposed "Federal Agency Retail Pharmacy Program" GSAR clause also would be invalid because it directly conflicts with the Federal Acquisition Regulations ("FAR"). Among other clauses, FAR 9.403 ("Definitions") expressly lists reimbursement transactions, such as insurance and government subsidies, within the definition of "nonprocurement transactions." By contrast, the Proposed Rule concludes that Federal agency reimbursement of a prescription drug claim made by one of the agency's beneficiaries constitutes a "procurement" transaction under the FSS contract and/or a depot contract. The Proposed Rule's conclusions in these regards are in direct conflict with the FAR.

Similarly, FAR 8.406-1 ("Order Placement") provides that an "ordering activity shall place an order directly with the contractor in accordance with the terms and conditions of the pricelists" and then proceeds to specify the terms that must be included in the order. Under the Proposed Rule, however, no order would be placed "directly" with the FSS contractor. Instead, orders would be "deemed" to occur when a Federal agency instructs the retail pharmacy to fill a prescription order requested by one of the Federal agency beneficiaries, a transaction to which the FSS contractor is not a party and over which it has no control.

The proposed clause tries to avoid this conflict with the FAR's ordering provisions, at least in part, by declaring in subsection (a) that certain FAR clauses that are not consistent with the proposed clause would not apply to Federal Agency Retail Pharmacy Programs.43 However, this approach would be insufficient. The FAR precludes agencies from promulgating supplemental acquisition regulations, such as the proposed clause, unless they are: (a) necessary to implement FAR policies and procedures within the agency; or (b) additional policies, procedures, solicitation

42 See Gen. Accounting Off., Pub. No. GAO/HEHS-98-176, Defense Health Care: Fully Integrated Pharmacy System Would Improve Service and Cost-Effectiveness 37 (June 1998) ("TRICARE contractors . . . are less able to negotiate deeper price discounts from drug companies without the ability to provide preferred or favorable status on a closed or incentive-based drug formulary").

4370 Fed. Rev., at \Q.OSO.

provisions, or contract clauses that supplement the FAR to satisfy the needs of the agency.44 Here, the proposed clause conflicts with the FAR, and would not further the needs ofthe GSA (the agency promulgating the regulation). Rather, by its terms, the clause would affect only the VA, the DoD, the PHS, and the Coast Guard - not the GSA. Because it does not comport with FAR requirements for supplemental agency clauses, the proposed clause would be an invalid exercise of the GSA's authority.45

C. The Proposed Rule lm1Jroperlv Augments ApDropriations

A Federal agency may not augment its appropriations by accepting money or gifts from outside sources without specific Congressional authorization.46 A corollary to this rule is that Federal agencies are not allowed to impose fees or accept voluntary services in the absence of statutory authority.47 In conflict with the anti-augmentation statutes, the Proposed Rule would permit the DoD (and other Federal agencies) to increase appropriations in the form of rebates collected from manufacturers.48 Because there is no statutory authority for the agencies to increase their appropriations in this fashion, implementation of the Proposed Rule would result in a violation of appropriations law.49

Related to the augmentation issue, the GSA claims that, because the Senate Report that accompanied the FY 2005 DoD Authorization Act decreased funding for the defense health program account and estimated savings from the TRRx Program,

"Congress has anticipated the extension of Federal pricing to the redesigned TPBP [TRICARE Pharmacy Benefit Program]." The Senate Report reflects an expectation of savings, not an endorsement of the TRRx Program. The FY 2005 DoD Authorization

44 FAR § 1.302 (2005).

45 See Service Employees Int'l Union v. Gen 'I Servs. Admin., 830 F. Supp. 5,9-10 (D.D.C. 1993) (GSA supplemental regulation held improper because it was contrary to aFAR clause and did not address a specific GSA need).

46 *See* 31 *V.S.C.* § 3302(b) (1982); 31 *V.S.C.* § 1301(a) (1992).

47 31 U.S.C. § 1342 (1996).

4870 Fed. Reg. at 19,046, 19,050.

49 *See Scheduled Airlines Traffic Offices, Inc. v. Dept. of Defense,* 87 F.3d 1356 (D.C. Cir. 1996) (fee
collected by government from travel agents under concession contracts and without Congressional authorization was an improper augmentation of appropriations and monies had to be returned to the Treasury).

Act does not contain any language supporting or authorizing the expansion FSS pricing to a retail pharmacy program. Rather, the citation is to a statement in a Senate Report, which was not enacted into law. 50

II. If Not Withdrawn. the Proposed Rule Should Be Clarified

In addition to our serious concerns about the GSA's legal authority to implement the Proposed Rule, the Proposed Rule is ambiguous in several respects and would cause significant operational difficulties if implemented. In the event that the rule is not withdrawn, as it should be, PhRMA respectfully requests that the GSA clarify and/or reconsider the following additional elements ofthe Proposed Rule.

1. Contract Modification. The Proposed Rule contemplates that a supplemental clause, known as the "Federal Agency Retail Pharmacy Program Supply Schedule," would be added to the GSAR and then could be incorporated into FSS contracts. The Proposed Rule is silent concerning the method that the GSA and/or the VA would use to incorporate the new clause into FSS contracts. In this regard, PhRMA emphasizes Clause 52.212-4, Contract Terms and Conditions - Commercial Items (FEB 2002) (TAILORED), a standard clause in the FSS contracts, which provides that "[c]hanges in the terms and conditions of this contract may be made only by written agreement of the parties." Accordingly, a unilateral modification of existing FSS contracts to add this clause would constitute a breach of contract. PhRMA requests clarification from the GSA that current FSS contracts will not be unilaterally modified to add the new clause. Further, phRMA requests that the GSA explain precise1y how it and/or the VA p1an to implement this clause ifthe Proposed Rule were to become final.

2. Scope of Coverage. By its terms, the proposed clause would apply only to "covered drugs" dispensed through qualifying retail pharmacy programs. PhRMA understands that the GSA intends for the rebate obligations prescribed in the clause to apply only to "covered drugs" as that term is defined in the VHCA. If our understanding in this regard were correct, then the scope of coverage of the new clause would be more limited than the scope of coverage of the Schedule 65 FSS contract into which the clause

50 Although legislative history may be useful "in resolving ambiguities and detennining congressional intent, it is the language of the appropriation act, and not the language of its legislative history, that is enacted into law." GAO Principles of Federal Appropriations Law, Vol. I, at 2-45 (3d ed. Jan. 2004) (citing *Shannon v. U.S"* 512 U.S. 573, 583 (199.'m.

would be incorporated. The VHCA defines "covered drugs" to include innovator dru~s (both single and multiple source) and biological and insulin phannaceutical products. I The Schedule 65 FSS contract covers not only "covered drugs," but also non-innovator multiple source phannaceuticals. PhRMA requests that the GSA confirm whether this distinction was intentional and, if so, to explain the rationale for limiting the scope of the proposed clause in this fashion.

3. Scope of the "Deemed Order" Concept. Both the preamble to the Proposed Rule and subsection (b) of the proposed GSAR clause note that covered drugs dispensed through a qualifying retail phannacy program "will be deemed to have been ordered by the Federal agency through the FSS contract, for the purposes of establishing price, delivery, and scope of coverage," but that the Proposed Rule "does not confer rights for any other purpose. ,,52 The GSA specifically should identify the "other purpose[s]" that are being referenced. The GSA also should explain how an agency instruction to a retail phannacy to fill a prescription from the phannacy's commercial stock can be deemed an order under the FSS contracts for certain purposes, such as to establish pricing, but not for other matters involved with the traditional ordering process.

4. Issues Concerning the Calculation of the Rebate Amount. Under the proposed clause, rebates would be calculated quarterly based on the difference between a benchmark price (either the actual sales price charged to the wholesaler or retail phannacy chain if known and auditable or the non-FAMP) and the lower of the FSS price or FCP for the drug in question. 53 PhRMA has a number of concerns about the proposed method for calculating the amount owed.

A. *Party To Determine the Benchmark Price.* The Proposed Rule does not specify the party that would determine the benchmark price that should be used. The GSA should clarify whether the Federal agency or the contract holder would determine whether to use the non-F AMP or the actual sales price in calculating the rebate amount. It should be the contract holder's decision regarding which benchmark to use, because the

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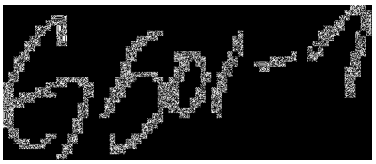
5138 D.S.C. § 8126(h)(2).

[52] 70 Fed. Reg. at 19,046, 19,050.

53 70 Fed. Reg. at 19.050.



contract holder is in the best position to know the prices that it receives for its products from wholesalers and/or retail pharmacy chains. 54

B. *The Rebate Formula Will Not Result in the FSS Price or the FCP*. The rebate formula apparently is intended to enable the Federal agency administering the retail pharmacy program to obtain the FSS price or the FCP for covered drugs sold through the retail pharmacy program. However, applying the formula described in the Proposed Rule will not achieve either of these intended effects.

Taking the DoD's TRRx Program as an example, the proposed calculation would not take into account the price that the DoD actually pays for drugs dispensed in retail pharmacies or that beneficiary cost shares in the TRICARE system are higher in the retail pharmacy sector than in the TMOP or MTFs. For this reason, it is possible that, under the tnmmla in the Propo~ed Rule, the DoD (though not the beneficiary) could end up paying luss for drugs dispensed in retail pharmacies than in the other points of service. Moreov~~r, the fonnula in the Proposed Rule would not result in the govcmment obtaining the FSS price or the FCP. Instead, the most that the rebate formula will obtain is an approximation of the FSS price or the FCP (that is, the difference between the non F AMP for a drug and the drug's FSS price or the FCP). We request clarification as to how the VHCA (or some other statute) authorizes a rebate methodology that would not result in the government obtaining either the FSS price or the FCP.

C. *The Rebate Formula Does Not Differentiate between Embedded and Ab!t'orbed IFF Payments.* Some FSS contractors incorporate the IFF payment into their FSS prices, thereby resulting in an FSS price that is increased by .5%. The purpose of this approach is to enable the ordering agency to pay the IFF to the contractor. The contractor then remits the IFF to the V A on a quarterly basis as required. Other contractors absorb the IFF payment, meaning that FSS prices are not adjusted to include payment of the IFF by the ordering agency. The formula in the Proposed Rule does not distinguish between those contractors who embed the IFF in their FSS pri(~es and those contractors who absorb the IFF payment. To ensure that the intent of the parties where the contractor embeds the IFF payment is maintained, the Proposed Rule should clarify

54 See, e.g.. TRICARE, Process and Procedures Guide for Manufacturer Refunds, Version 2.1, 11. *available at* http://www.tricare.osd.mil/phann_mfgldownloads/Policies_and_Procedures_ Guide _ 2-1.pdf (last updated Mar. 24, 2005) (indicating that choice of benchmark price would be "at the discretion of the manufacturer").

that the benchmark price for the rebate for contractors who embed the IFF is the negotiated FSS price for each drug plus .5% (the "IFF" amount).

D. *The Rebate Formula Could Lead to Unreasonable Results.* Under the VHCA, it is possible for the FCP for certain drugs to be artificially set at $.01. This result, known as "penny pricing," occurs when the price of a covered drug substantially increases fTOm one year to the next such that the additional discount mandated by the VHCA causes the FCP for the covered drug to be a negative number. In such circumstances, VA by policy sets the FCP for the covered drug at $.01.55 For those drugs that are penny priced, the formula in the Proposed Rule could lead to absurd results. The benchmark price (either the actual sales price or the non-FAMP) would far exceed the FCP (which would be $.01). Accordingly, the amount owed for such drugs could be considerably higher than the government's acquisition costs, particularly if the beneficiary *cost* share for the dn.Jgs is higher, s~ch as for (J Tier 3 drug (the tier wi.th the $22 C(Jst share) on the D(,D's uniform iormuiary. Such a result cuuld not possibly be intended by law and is further reason V',hy the rule is irratioIlal and unauthorized.

5. Issues Conceming the Schedule for Submission of Rebates, Payment of the IFF, and the Disputes Process. The Proposed Rule contemplates that a Federal agency administering a retail pharmacy program would provide utilization flat file layout reports to FSS contract holders on the 15th day of the first month after the close of a calendar quarter.[56] The manufacturer would then have 70 days to calculate the rebate amount owed, reconcile the calculation with the Federal agency calculation, and pay the rebate. 57 Thus, thl' rebate amount would be due 85 days after the dose of each calendar quarter. Additionaily, we understand that the proposed clause would require FSS contract holders to report retail phannacy sales and pay the IFF on those sales in accordance with the V A's variation of clause 552.238-74, Industrial Funding Fee and Sales Reporting (JUL 2003) (VARIATION), which requires FSS contract holders to report their quarterly sales and make the IFF payment within 60 days ofthfJ close of the reporting period. As we understand the proposed GSAR d:mse, the 60-day reporting requjrl~mern would be tnggered for retail pham1acy saies at tJ1{; ~uct of the quarter in wh:ch rhe r<.:bale

___a___ ~____

55 See. e.g., L~tter from '.ViIliam E. Thomas, Jr.. Assistant General Counsel; Dep't. of Veterans Affairs, to
Manufacturer (Dec. 30, 1992). (Attached as Exhibit E).

5670 Fed. Reg. at 19,050.

5770 Fed. Reg. at 19,051.

calculation is made, not at the end of the quarter in which the retail pharmacy transaction occurs. For example, as we read the clause, retail pharmacy sales that occur in the fourth calendar quarter of a year need not be reported until 60 days after the close of the first calendar quarter of the following year. PhRMA requests clarification that its understanding in this regard is correct.

A related issue arises if a contract holder and the Federal agency disagree about the amount that is due for a particular quarter. Under those circumstances, the proposed clause as written would require the contract holder to pay the rebate according to the agency's calculation (including the disputed amount) and then use "best good faith efforts" to resolve the dispute within 60 days. 58 Only after the completion of the 60-day negotiation period would the contract holder be permitted to file a claim pursuant to the Disputes clause. PhRMA has three concerns with this provision.

A. *Payment of Rebates During Pendency of a Dispute.* In the event of a disagreement, the proposed clause would require FSS contract holders to pay the entire rebate amount, including the portion in dispute, pending resolution of the dispute.59 This approach is different ITom the approach taken in connection with the Medicaid Rebate statute. In the event of a dispute concerning the amount of the rebate that is due under the Medicaid Rebate statute, the Rebate Agreement requires manufacturers to pay only "that portion of the rebate amount claimed which is not disputed" and to pay any balance plus interest by the "due date of the next quarterly payment. . . after resolution of the dispute. ,,60 A similar approach should be adopted here.

B. *IFF Refunds if Contractor Prevails in a Dispute.* The retail pharmacy clause as currently written is silent on whether the V A would be required to remit the affected portion of the IFF (with interest), either by refund or offset, in the event that good faith negotiations or a court decision subsequently result in a reimbursement of part of the refund to the contractor. If the Medicaid Rebate approach were adopted, contract holders could make disputed refund payments and IFF payments during the quarter immediately following the resolution of the dispute. Ifthe GSA chooses not to adopt the Medicaid

5870 Fed. Reg. at 19,051.

5970 Fed. Reg. at 19,051.

60 Sample Medicaid Drug Rebate Agreement § V(b), *available at* http://www.cms.hhs.gov/medicaidfdrugsfrebate.pdf.

Rebate approach, at a minimum the retail pharmacy clause should be modified to require the V A to remit the portion of the IFF that is attributable to disputed refund amounts on which the FSS contract holder's position ultimately prevails, plus interest.

C. *The Proposed Clause Would Be Inconsistent with the Contract Disputes Act.* The 60-day mandatory negotiation period would be inconsistent with the Contract Disputes Act ("CD A"), 41 D.S.C. § 601, *et seq.* In particular, section 605(d) of the CDA provides in pertinent part:

> Notwithstanding any other provision of this chapter, a contractor and a contracting officer may use any alternative means of dispute resolution under subchapter IV of chapter 5 of Title 5, or other mutually agreeable procedures, for resolving claims. The contractor shall certify the claim when required to do so as provided under subsection (c)(1) of this section or as otherwise required by law.

While this provision authorizes voluntary use of alternative dispute resolution procedures, it does not permit mandatory periods of negotiation or other administrative exhaustion requirements beyond those required by the CDA. For this reason, the GSA should delete subsections (h)(2) and (h)(3) of the proposed GSAR clause and replace them with a requirement that FSS contract holders process all disputes concerning the proper amount of the rebate owed under the retail pharmacy clause through the Disputes clause in the FSS contracts. PhRMA agrees, however, that resolution of such disagreements through good faith negotiations would be preferable to a formal dispute. The GSA could make such an option available to the parties by adding a provision that would authorize voluntary negotiation of disagreements over the amount of a rebate, but which would make clear that contractors would not have to exhaust that voluntary negotiation process before initiating the disputes process.

J[i]

6. *Clerical Revisions.* The proposed clause contains two references to the DoD that PhRMA believes may be clerical mistakes. First, in subsection (g)(I)(iv), the clause refers to the Department of Defense's Accrual Fund and the Defense Health Program account as the source of funding for a retail pharmacy program.61 These accounts would be available only for the TRRx Program and would not apply to retail pharmacy

61 70 Fed. Reg. at t 9.050.

programs administered by the V A, the PHS or the Coast Guard. Second, subsection (g)(3) would require that rebate payments be "received by DoD" not later than 70 days following the date of the utilization file for the quarter.62 Again, we assume that the DoD would be the recipient of rebates only for the TRRx Program and not for any other qualifying retail pharmacy programs.

7. References in the Clause to Terms and Conditions of Commercial Agreements. The proposed clause refers in subsection (d) to the tenns and conditions of commercial agreements between the FSS contract holder and the retail pharmacies or wholesalers.63 Specifically, that subsection would provide that the time and methods of payments to the FSS contract holder for FSS items deemed to have been ordered through the retail pharmacy program would be detennined in accordance with the tenns and conditions of commercial agreements between the manufacturers and the retail pharmacies or their wholesalers. The tenns of a commercial agreement cannot control parties' obligations under an FSS contract. The GSA's reliance on the tenns of the contracts between manufacturers and retail pharmacies or wholesalers further demonstrates that there is no contract under which Federal agencies procure the covered drugs that would be dispensed through a retail pharmacy program. In the absence of such a contract, the Proposed Rule IS Improper.

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6270 Fed. Reg. at 19,051.

63 70 Fed Reg. :at 19,050.

III. Conclusion

PhRMA appreciates the opportunity to submit these comments on the Proposed Rule. As explained above, the Proposed Rule raises a number of important policy, legal, and implementation issues. PhRMA remains committed to working with DoD, V A, and others in the Federal government to develop alternatives to the Proposed Rule that can accommodate the concerns raised by all parties in a manner that is consistent with existing laws.

We appreciate your consideration of our comments.

Sincerely,

Diane E. Bieri
Vice President and
Acting General Counsel

Richard I. Smith
Senior Vice President Policy,
Research, and Strategic Planning

cc: (by hand detivery)

The Honorable David Safavian
Director, Office of Federal Procurement Policy

PhRMA's Comments on GSAR Case No. 2005-G501

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B	Letter from William E. Thomas, Jr., Assistant General Counsel, Dep't of Veterans Affairs, to Lt. Co!. Henry L. Smith, OASD (HA) HSF/MCO, the Pentagon.	July 28, 1994
C	Letter from Steven Thomas, Acting Executive Director, V A National Acquisition Center, to Manufacturer of Covered Drugs.	Oct. 14, 2004
D	White Paper for the Office of the Secretary: TRICARE and Federal Ceiling Prices.	Oct. 10, 2002
E	Letter from William E. Thomas, Jr., Assistant General Counsel, Dep't of Veterans Affairs to Manufacturer.	Dec. 30, 1992

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DEPARTMENT OF VETERANS AFFAIRS
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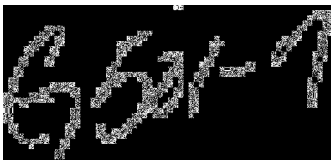

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In Reply R8IIr To:

Robert D. Seaman, Esq. General
Counsel
TRICARE Management Activity
Skyline Five, Suite 810
5111 Leesburg Pike
Falls Church, Virginia 22041-3106

Dear Mr. Seaman:

I have reviewed your letter of September 17, 2001, asking that the Department Qf Ve~rans Affairs N A) concur In your opinion that purchases of covered drugs under the retal portion of a proposed new TRICARE Pharmacy Benefit Program (TPBP) qualify for Federal celing "prices (FCP) under the Veterans Health Care Ad. of 1992 NHCA), Section 603, 38 U.S.C. 8126. I recently shared your letter with VA's Public law 102-585 (P.L.) Policy Group at their annual meeting, and they reviewed the arguments presented in support of your position a8 well 88 the diagram attached to your letter.

After some discussion, the Policy Group requested that I obtain further input

from your agency concerning the nature of your request and your understanding of how the TPBP wli function. PreUmlnarly, the Policy Group wishes to know whether your agency Is requesting 8ppRMII for fuU Federal Supply Schedule (FSS) prick1g for all retaD prescription purchases under the TPBP or whether your position is simply that such purchases are entitled to FCPs under the VHCA.

ciate receiving your comments on what

A

has been the standard VA interpretation of the statutory definition of -depot',

contained in 38 U.S.C. 8126(hX3). VA h88 consIatantIy Interpreted the two

prongs of that definition 88 being limited to centralized commodity management

systems through which covered drugs are: (A) received, stored and delivered to a

listed Federal agency through a federaMy-owned warehouse system or a

commercial warehouse system operating under contract with the procuring

Federal agency, or (8) delivered directly from the manufacturer or Its agent to a

listed Federal agency's ontertng activity at its purchasing address. Prior to

receiving your letter, we have never vfewed a Federal agency's pharmacy benefits office (PaO) and its contracted commercial pharmacy benefits manager

(PBM) 88 a -centralized convnodlty management system- within the definition of

-depot-. We a'so have not previously viewed the term 8ent1ty" as being 88

unfimited and broadly defined a8 you state in your IeUer.

Also, the Policy Group would appre, J

r. 2.

Robert D. Seaman,

Esq.

Because your agency shared detals of the !18W TPBP with some

representatives of the phannaceutical industry, private law firm attorneys in

Washington, DC have begun to discuss the program and react to it. RecenUy,

one such attorney described the program as being merely -an insurance reimbursement scheme-. The P.L Policy Group would appreciate receMng your reaction to that characterization, along with a summary by TMA of al Industry reactions noted during any meetings with representatives of covered drug manufacturers. Also, a practical question has been raised 88 to how OoO's PBO . would deal with package size differences between FSS NDC units and retaU pharmaCy dispensing units, ~ the PBO applies for FSS or FCP -rebates-.

Finally, tne POlicy Group Is puzzled by your diagram'S treatment of

prescriptions filled by -non-network ratal pharmacies-. It Is the Policy Group's.

opinion that such phannacles have no contractual relationship whatsoever with

DoD's PBe and/or its contracted PBM and, thus, wi be dispensing

phannaceuticals that are not covered by the VHCA.

I understand that T~ is interested in obtaining an opinion from VA on the matters specified In your letter a8 quickly as possible. However, as you know from the history our two agencies' Interaclions concerning TRICARE Pharmacy Benefits, the TPBP presents serious and difficult questions of application of the VHCA, and the Policy Group wishes to be fuDy Informed prior to making any recommendations. Once I receive your response to this letter, I wII convene the Policy Group and attempt to obtain a prompt decision from them on the position that you set forth. Thank you for your cooperation In this matter.

Slncerety

yoors,

Phlilipa l. arson Assistant
General Counsel

cc: Deputy Assistant General Counsel
(025C) Associate Chief Consultant, PBM
(1190) Director FSS Contracting (90N-M 1)
Audit Team Leader (52C)
PBM Data Base Manager (119D)
Senior Contract Attorney (025NAC)

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DEPARTMENT OF VETERANS AFFAIRS
OffiCI of G ..... , Counsel
PO 10K 16 Hines Il 60141

July 28, 1994

In Rap"' Ref., To: 025

Lt. Col. Henry L. Saith OABD (RA)
HSF7KCO
The Pentagon, Roo.. IB651
Washington, DC 20301-1200

RE. Applicability of Public Law 102-585 to USTP.s and DoD Health Care Contractors' Drug Procurements

Dear Lt. Col. Saith.

Pursuant to our telephone conversation on July 26, 1994, I 41ft writing to request the position of the Departaent of Defense (DaD) on the applicability of Section 603 of the Veterans Health Care Act of 1992 (P.L. *102-5851* 38 U.S.C. 8126 (a) et seq.) to covered drug procur...ent. made by Uniformed Services !reatment Facilitie8 (USTFs), the Civilian Health and Xedical ProgrUi of the Unifora Service. (CHAJlPUS) and its aail order prescription contractor, Diagnostek, Inc./Health Care Services, Inc. (HCS).

As you know, P.L. 102-585 requires all manufacturers of covered drugs who wish to receive pBJIR8nt for their drugs sold to Xedicaid Plans, the Departlient of Veterans Affairs (VA), the Public Health Service (PHS), DaD or any entity that receives funds under the Public Health Service Act, to enter into an agr ..... nt with VA to grant a ainillwa 24 percent discount aD covered drugs to DaD, VA and PHS. The Law also requires th_ to aake available all of their covered drugs on the pederal Supply Schedule (PSS) adainistered by VA. The Statute does DQt require manufacturers to grant the discount to any gov&rJUI8nt agencies other than VA, DaD and PHS (includinc; the Indian Health Service) or to grant it to government contractors authorized to use the FSS. (38 U.S.C. 8l26(a)(2) and (b).)

To accomaodate the limited nature of this congressionally imposed covered-drug discount, VA has allowed manufacturers to choose whether they will, for ease of adainistration, provide the discount to all users of the FSS or whether they will print two price lists--one containing Federal ceiling prices for VA, DaD and PHS, and the other cC!ntaining the standard' FSS prices negotiated according to GSA guidelines. Approximately 35 IU.nufacturers have elected to print two price lists under the PSS and, thus, to limit the beneficiaries of the discount required by the Statute.

...--..

July 28, 1994

Lt. Col. Henry L. Smith
OASD (HA) KSF1KCO

VA has the responsibility to administer and enforce Section 603 of P.L. 102-585, and, in that role, has received inquiries and complaints from covered drug lIanufacturers regarding recent bulletins and instructions issued by COD's Defonee Personnel Support Center [redacted] .ay 29, 1 Contracting Officer Roger Dixon of DPSC wrote a meD DPSC DAPA Bolders and Pd... Vendors" infoning them that USTF facilities are eligible to receive the same Government pricing structure offered to all other DaD facilities using the DPSC Prime Vendor progr... II Also, on July 25, 1994, Contracting Officer Paul Vaaque. wrote to drug manufacturere announcing the award of a ..il order pharllacy contract to Diagnostek, Inc./Health Care Services, Inc. (HCS) and infor8ing them that the contract authorizes the vendor to utilize Government sources of supply, as directed by Congress. The letter stated that "HCS may be contacting you for the procur888nt of pharmaceutica18... I. and that " [t]ha procuring of the8e phax.aceutica18 i8 80lely the responsibility of HCS. .. With regard to payment, "' DPSC shAll not 00 included in any of these arrangements."

Syntex Laboratories, Inc., a dual pricing covered drug -.anufacturer, has asked VA whether it is statutorily required ~nder DPSC'. instructions to sell its covered drug8 to CHAXPOS and USWs at Federal ceiling prices contained in its price list for VA, DaD and PHS. At present, we lack sufficient information to answer th.1s question. Consequently, VA would like to receive information and input in writing from DaD on two questions.

1) Does DoD intend that USTFs and CHAJfPtJS contractors, as well aa 88il order pharmacies with DaD contracte, purchase covered drugs in the D8II8 of DaD at etatutoq Federal ceiling prices (when these are the lowest prices available) or does COD intend to have the8e organizations purchase drugs at the regular FSS neqot~ated contract price7

2) If the above organizations Are to procure covered drugs at Federal ceiling prices, how does DaD propose to set up the8e transactions and interpret the Statute 80 a8 to extend the discount to USWs and CHAMPUS? (Please also 8end copie8 of standard DoD agre_nts with the8e organizations.)

I

July 28, 1994

Lt. Col. Henry L. Smith
OASD (HA) HSP
7HCO

1 would appreciate it if you would c088Unicate these questions to the DaD attorneys responaible for dealing with these aaatters so that VA can respond to Syntex'. and other manufacturers' inquiries a. soon aa pos8ible. Xelbourne A. Noel, Jr.. of thi8 office would be happy to di8cu8. interpretation and application of the Statute with any DaD personnel. He..y be reached at (708) 216-2504. Please be assured that VA'. 90al is for the Governaent to derive from P.L. 102-585 the 8&Xi8U8 financial benefit that can be ju.tified by its lanC)Uage and the intent of Conqress in drafting it.

Sincerely yours,

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1I A.sistant General Counsel

eel Office of General Counsel (025HAC)
Associate DAB for the)JAC (90N) .
Director, Acquisition Analysis'
Liai80n Staff (96)
Chief, Clinical Pharmacy (lIIH)
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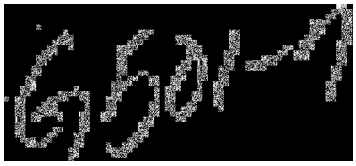


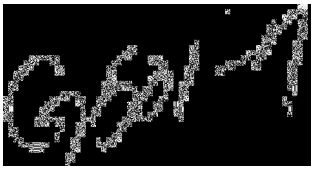
In Reply Rer.r To:

. October 14, 2004

Dear Manufacturer of Covered Drugs:

As you are aware, the Veterans Health Care Ad of 1992 (VHCA), P.L. 102.585, Section 603 (38 U.S.C. 8126), and the Master Agreement (MA) and Pharmaceutical Pricing Agreement (PPA) that your company signed with the Department of Veterans Affairs (VA), require that Federal ceiling prices (FCPs) must be applied to covered drugs purchased by the Department of Defense (DoD) through depot contracting systems. TRICARE Management Activity (TMA) is the DoD organization established to manage DoD's comprehensive health care program known as TRICARE, which includes an alternate health care system mandated by Congress for U.S. armed forces personnel. retirees, and dependents who do not reside near a military treatment facility. (See Chapter 55, Title 10, United States Code.) The TRICARE program involving health care furnished outside of military treatment facilities has traditionally been implemented through contracts with large civilian managed health care organizations, which. in the past, provided pharmaceuticals to DoD benefICiaries with no dired involvement by DoD offICials. Under this prior approach, TRICARE regional contractors entered into their own agreements with providers of pharmaceuticals, and DoD did not directly or indirectly control payments for its TRICARE beneficiaries' drugs. Furthermore, DoD was not entitled to receive each dollar saved, had managed care contrados been permitted to buy drugs
and prescriptions at Government discounts. Under these circumstances, VA . determined that the VHCA requirement for a depot contracting system did not exist and TRICARE was not able to benefit from Federal covered drug pricing through its original managed care contracts. (See '"Dear Manufacturer letter" of October 7,1996.)

Effective May 3, 2004, TRICARE restructured its Pharmaceutical Benefit Program in response to congressional direction to redesign the military and contractor pharmacy system. It carved the benefit out of its regional contraots, set up a DoD Pharmacy Benefit Offace to control payments for benefICiary scripts and hired a Pharmacy Benefits Manager (PBM) to handle most administration work involved in contracting with a large number of retail pharmacies (collectively, Mthe network") to fill TRICARE benefICiary scripts. TMA followed commercial models in devising its new plan, allowing network pharmacies to



2.

Dear Manufacturer of Covered Drugs

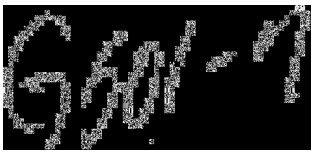
obtain drugs in the usual fashion and then applying the Federal discount after scripts were filled, through refund claims submitted to manufacturers by the pao itself. This approach eliminated the possibility that commercial contractors or subcontractors of 000 might profit from application of FCPs to TRICARE purchases.

TMA presented the restructuring plan to VA in 2002, with a request that VA approve application of FCPs to TMA purchases of covered drugs obtained by its beneficiaries from subcontracted retail pharmacies. On October 24,2002, after consideration of the functional elements and the legal issues inherent in the plan. the Secretary of VA decided that TMA's RetaH Pharmacy Benefit Plan (TRRx) was a centralized pharmaceutical commodity management system that met the definition of -depot- contracting system set forth In 38 U.S.C. 8126(h)(3). Consequently. covered drug prescription purchases under TRRx, authorized and paid for by TMA's Pharmacy Benefits OffICe. qualified for FCPs from commencement of the TRRx program on June 1. 2004. However, to avoid complicating and delaying manufacturers' 2004 annual non-F AMP reports, TMA has agreed not to demand refunds resulting from application of FCPs to retail network purchases until after September 30. 2004, the cut-off date for transactions included in the 2004 reports.

It is within the authority of the VA Secretary, in administration of the VHCA and as issuer of the MAs and PPAs, to determine whether one of the four VHCA Federal agencies has established a qualifying depot contracting system under which covered drugs may be purchased at a discount. (See 38 U.S.C. 8126(a), (e)(3) & (4), (1), (g), and (h)(5).) Once that determination is made, the Federal agency (in this case, 000) is authorized to receive FCPs on covered drugs by operation of law and the express terms of the Master Agreement executed by VA and each drug manufacturer. No published notice or rulemat<ing is required to make effective the policy and requirements already established by statute and written agreements.

Because TMA's retail pharmacy network covered drug purchases will be made initially at commercial prices, TMA will obtain Federal ceiling pricing for these purchases by fOIW8rding detan~ pur~hase data to manufacturers each month and then requesting refunds on a quarterly basis to achieve Federal pricing. TMA's plan for transmitting data and collecting refunds is set forth at the TMA web site: hftp://www.tricare.osd.miVaharm mfQ/defauft.cfm.

In addition to calculating covered drug refunds using TMA's monthly purchase data feeds. manufacturers who sell and/or deliver their drugs to network pharmacies and others through wholesalers will need to adjust their



3.

Dear Manufacturer of Covered Drugs

sales data used in current non-FAMP computations in order to ensure that TMA purchases are properly reclassified as sales to the Government. Once TMA identifies aggregate purchases of NDC packages of covered drugs as Government purchases, manufacturers will have to remove these purchases from net wholesale sales in order to arrive at correct non-FAMP figures for each NDC of each drug. Manufacturers may assume that TMA's reported purchases occurred during the non-FAMP reporting period in which the TMA data was received. Except for adjusting the third-quarter 2004 non-FAMP in Nov. 2005. and except to correct fundamental computation errOt'S in later quarters. there will be no requirement to re-open and adjust already filed non-F AMP reports to accommodate TMA data received after filing. Accounting methods for removing TMA purchases from wholesale sales may vary by company, depending on systems set-up. Please find attached to this letter some "Non-FAMP Calculation Considerations. and "Non-FAMP Impact Scenarios. to assist you with devising a method for removing TMA purchases from wholesale sales.

If you have any questions concerning the above policies, please telephone
Mel Noel at (708) 786-5167.

Sincerely,

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Acting. Executive Director
VA National Acquisition Center

1 Enclosure

G501-1

Non-FAMP CalculationConsiderations

- If TRRx sales included product delivered through wholesalers (as opposed to direct sales to pharmacies) and Mfa uses wholesale sales to compute non.FAMPs, then these TRRx sales and units must be removed from wholesale sales during current non.f AMP calculauons
- If products sold to TRRx were originally booked as direct saJes to a retail chain, it is likely that these sales were already excluded from the non..F AMP calculation
- Jfthe TRRx transactions cause anomalies in the non-fAMP that are not taken care of through the normal chargeback smoothing methodology, communicate those issues to Me) Noel at the National Acquisiuon Center for consideration.

Non-FAJ\fP Impact Scenario.

. Scenario 1, Method 1
  - Manufacturer sells only to WholesaJers
  - Manufacturer has no contractual agreements with the retail pharmacies - Manufacturer nonnanv removes FederaJ saJ~ by adjustinll wholesale sales at contraCt selJimz price. in this case the assumed FCP of $72
  - In absence of known saJe price to TRRx NetWOrk. the manufacturer calculates TRRx refund using Non.FAMP = 594.74
  - TRRx reports to manufacturer that retail pharmacies purchased J ,250 units of the NDC
  - Given the asswnptions the actual refund to Tricare would be J ,250 x ($94.74-$72.00) ... $28,425
  - When the manufacturer does not know the price to the retailer, the rerw:.. amount to Tricare that was figured based aD nOD..FAMP cannot be used 10 rc-state the nou.FAMP. - The amount used to restate the non.f AMP must be at WAC.
  - The fact that Tric81e has given Manufacturers a lesser price (Non-f AMP) to calculate the refund CaMot transJate to an assumption that the original sale occurred at other than WAC

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. Chanles to non-FAMP (Scenario 1, Method 1)

- Government sales at FCP are increased by 1,250 units at $72.00, units are increased by J ,250
- An additional reduction is made to account for the TRRx refund wbich is the difftrence between WAC and the FCP times the number of units or ($100-$72) x] ,250 - $35,000

Orilln.. CalcuJatioD

	DoBars	Units
Wholesale SaJes (WAC - $100)	$10,000,000.00	100,000
Less:		
Prompt Pay Discount (2">	$200,000.00	
Government Sales 0 $12.00	5360,000.00	5.000
PHS (0 602 price $75.00)	$2,250.00	30
Chargebades	5523,075.00	
SubtotaJ Reductions Non-FederaJ DoUars &I Units non-FAMP	$1,085,325.00	
	$8,914.675.00	94,970
	$93.87	

Revised CalculatioD

	DoUars	Units
WholesaJe SaJes (WAC" $100)	$10,000,000.00	100,000
Less:		
Prompt Pay Discount (2">	$200,000.00	
Government Sa)es ▪ snoo	$450,000.00	6,2501
PHS (0 602 price $75.00)	$2,2S0.00	30
Chargebacb	5523,075.00	
TRRx Refund. WAC	535.000.00	
Subtota] Reductions Non-Federa) DoBus &I Units non-FAMP	*$1,210,325.00*	
	$8,789,615.00	93,720
	$93.79	

. Scenario 1, Metbod :z

- Manufacturer seUs onJy to WhoJesaJm
- Manufacturer has no contractuaJ agreements with the retaj) pharmacies
- Manufacturer nonnaJlv removes Federal *sales bv* adiustina wholesale sales and c:haflzebacks
- The FCP - $72
- In the absence of known seJes price to TRRx NetWork, Manufacturer uses

Non-FAMP a= $94.74

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. Changes to non.FAMP (Scenario 1, Method 2)

- Govenunent sales at "WAC" is increased by],250 x $100.00, Units are increased by 1,250 - The TRRx refund for bookkeeping purposes is calculated as in Method I. - No further adjustment js necessary because the chargeback system is not affected by the transaction.

Orieinal CaJcuJatioD

	DoDars	Units
WholesaJe Sales (WAC. 5100) Less:	$10,000,000.00	100,000
Prompt Pay Discount (2")		
Government Sales (0 WAq PHS	$200,000.00	
(OWAq	$500,000.00	5,000
Chargebacb	$3,000.00	30
(Less Gov and PHS Chargebacks)	*$523,0'15.00*	
Subtotal Reductions	-$1.0,750.00	
Non--FederaJ DoDars &r Units	51,085,325.00	
non.FAMP	58,914,675.00	94,970
	$93.81	

Revised CaJ~uJatiOD

	DoDus	Units
WhoJesaJeSaJes (WAC. $100) Less:	$10,000,000.00	100,000
Prompt Pay Discount (2">		
Government SaJes CO WAq PHS (0	5200,000.00	
WAq	$625,000.00	6,2501
ChugebacJcs	$3,000.00	30
(Less Gov and PHS aarlebacks)	5523,075.00	
Subtobd RedUCtioN.	-$140,750.00	
NOJ1o.federaJ DoDars at Units	$1,210,325.00	
non.FAMP	$8,789,675.00	93,720
	593.79	

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- Scenario 2, Metbod J

  - Manufacturer sells onJy to Wholesalers
  - Manufacturer has agreement with the retail pharmacy at 8 sales price of 595.00
  - Manufacturer normallv removes Federal sales bv adiustinR wholesale safes at Government contract seJling urice. in this case the FCP t:: $72
  - TRRx rcpons to manufacturer that retail pharmacies purchased] ,250 units of the NDC
    - Given the assumptions (wholesale sales only, known contract price to retail pharmacy) the actual refund to Tricare would be 1,250 x (595.00 572.00).528,750 .
  - When the manufacturer knows the price to the retailer, those transactions wi)) need to be replaced with Tricare transactions.

- Changes to non.FAMP (Scenario 2, Metbod 1)

  - The chargeback transactions are decreased by the charge backs for those urnts now cJassified as Tricare (1,250 x 55.00 ., 56,250)
    - An additional reduction is made to 8CCOWlt for the TRRx refund which is (for bookkeeping pwposes in this scenario) the difference between WAC and the FCP times the number of units or ($100.$72) x],250 - 535,000
    - The fact that Tricare has given Manufacturers a lesser price (pharmacy contract price) to calculate the refund cannot translate to an assumption that the original sale occuncd at other than WAC.

Orielna) Calculation

	Donars	Units	
WholesaJe Sales (WAC. 5100)	510,000,000.00	100,000	
Less:			
Prompt Pay 1)jscount (2)	5200,000.00		
Goverr.ment Sales. $'72.00	S360,000.00	5,000	.,- .
PHS (0 602 price $75.00)	52,250.00	30	,.... .
Chargebacks	$523,075.00		
Subtotal Reductions	51,085,325.00		
Non-Federal Dollars at Units	$8,914,675.00	94,970	
non.FAMP	$93.81		

Revised Calculation

	Do11an	Units
Wholesale Sales (WAC. $1(0)	510,000,000.00	100,000
Less:		
Prompt Pay Discount (2")	$200,000.00	
Government Sales 0 $72.00 PHS	$450,000.00	6,2501
(0 602 price $15.00)	52,250.00	30
Chargebadcl	$516,825.00	
TRR:x Refund 0 WAC	535,000.00	
Subtotal Reductions	$J,204,075.oo	
NOr1*Federal DoUars at Units	$8,795,925.00	93,720
non-FAMP	593.85	

. Sccnario 2, Meihod 2

- Manufacturer sens onJy to WhoJesaJers
- Manufacturer has contrnctua1 agreements with the retaH pharmacies at a sales price of $95
- Manufacturer nonnallv removes Federal sales bv adiustinll wholesaJe saJes and chareebacks
- The fCP = $72; Non-f AMP = $94.14

. Chanaes to nOD..FAMP (Scenario 2, Method 2)

- Government sales at "WAC" is increased by 1,250 x $100.00, Umts are increased by *I,2S0* - The TRRx refund for bookkeeping purposes is calculated as in Method 1. - No further adjustment is necessary because the cbargeback system is not affected by the transaction

Orfldnal Calc:ulatfoD

	DoUIJ'I Units	
WholesaJe SaJes (WAC. $100) Less:	$10,000,000.00	100,000
Prompt Pay Discount (2%)	5200,000.00	
Government Sales (0 W Aq PHS	$500,000.00	5,000
(OWAq	53,000.00	30
Chargebacks	$523,015.00	
(Less Gov and PHS Chargebacks)	.$140,750.00	
Subtotal Reductions	$1,085,325.00	
Ncin-FederaJ DoDars at Units non--FAMP	58,914,675.00	94,970
	$93.81	

Revised CalcuJatioD

	DoUan Units	
WhoJesaJe Sales (WAC - $]00) Less:	$1£1,000,000.00	
Prompt Pay DiscOUJ\t (2%)	100,000	
Government Sales (0 WAq PHS	5200,000.00	
(OWAq	$625,000.00	6.250]
Chargebacks	$3,000.00	30
(Less Gov and PHS O\argebacks)	$5]6,825.00	
Subtotal Reductions	-$140,750.00	
Non-FederaJ DoUars ar Units non-FAMP	$1,201,075.00	
	$8,795,925.00	93,720
	$93.85	

WHITE PAPER FOR THE OFFICE OF THE SECRETARY
TRICARE AND FEDERAL CEILING PRICES

OCTOBER 10, 2002

PURPOSE:

To inform the Secretary of the facts and circumstances surrounding a decision of the VA P.L. 102-585, Sec. 603, Policy Group at Its September 24,2002, annual meeting regarding requests for favorable Interpretation of the P.l. received from DoD's TRICARE Management Activity (TMA) between September 17,2001, and June 28, 2002. TMA has asked that VA concur In Its opinion that purchases of covered drugs under the retail portion of the new TRICARE Phannacy Benefits Program (TPSP) qualify for Federal Ceiling Prices (FCP) under the P.L. (Veterans Health Care Act of 1992; 38 U.S.C. 8126).

POLICY GROUP DECISION:

After considering TMA's position and a PhRMA letter opposing the Idea, the Policy Group agreed that TMA's interpretation of the P.l. was reasonable and that DoD beneficiary prescriptions filled under the retail portion of the new TPBP
will qualify for Federal CeDing Prices. (The Policy Group Includes representation
from all the elements of VA that are stakeholders In the drug pricing statute, i.e., VHA's. PBM, OA&MM's NAC, the OffICe of Inspector General (52C), and the Office of General Counsel (025).

DISCUSSION OF LEGAL QUESTIONS:

There can be no real question that, when Congress .enacted P.L. 102-585, Sec. 603, in 1992, their Inclusion of DoD as. one of the benefiting Federal activities meant that Congress expected aD CoD expenditures for covered drugs to be affected by the calculations which yield Federal Ceiling Prices. The questions that arise have to do With the strict or liberal interpretation of the statute's wording that describes the acquisitions that are the subjects of a Master Agreement (MA) and Phannaceutical Pricing Agreement (PPA). The statute, at Sec. 8126{aX2), sots forth one *01* the requirements of the MA as follows: "with respect to each covered drug of the manufacturer procured by a Federal agency described In subsection (b) pncludlng. CoD) on or after January 1, 1993, that is purchased under depot contracting systems or listed on the Federal Supply Schedule, the manufacturer has entered Into and has in effect a pharmaceutical
pricing agreement with the Secretary....

The prlmarv legal Issue Is whether II DoD Pharmacy Benefits Office (PSO) mochanlsm for filling DoD beneflclarv prescriptions throuah a commercial retail phannacy network and contracted pharmacy benefits management firm (PBMJ constitutes a Durchas8 by DoD' under II depOt contractlna sYStem.

1. The definition of depot in Sec. 8126(h)(3) asserts that "depor means a "centralized commodity management system through which coyered drugs procured by an agency of the Federal Government are- (A) received, stored, and delivered through- (i) a federally owned and operated warehouse system, or (iI) a commercial entity operaUng under contract with such agency; or (B) delivered directly from the commercial source to the entity using such. covered drugs." TMA's TPBP does not Involve a federally owned and operated warehouse system, and, while it does Involve a commercial warehouse system, that system does not have a direct contract with DoD. Nevertheless, prong (B) of the definition is broad enough to Include the TMA plan. The commercial prime vendor or warehouseman serving the pharmacies can certainly be considered a commercial source, and the dispensing retail pharmacy fits within the description "entity using such covered drugs". This very broad language was most likely adopted by Congress to accommodate possible future pharmaceutical distribution techniques deyeloped in this country and ultimately participated in by
the Government. The TPBP is one such covered drug prescription distribution method.

2. Under TMA's plan, the acquisition of beneficiary prescriptions is a procurement by DoD. TPBP Is a centralized system, I.e., "depot", for the acquisition, delivery, and distribution of Prescriptions by DaD on behalf of its beneficiaries throUgh the use of a DaD PBO and a contracted PBM with a retaD pharmacy network. Additionally, 000 appropriated funds will be used by the PBO
and PBM to pay for all TRICARE prescriptions and the PBM will be paid a negotiated administrative fee for petfonnance of all services under the contract, including providing the retail pharmacy network and functioning as a fiscal intermediary for DoD. The PBM fee will not be related directly or indirectly to total phannaceuticat costs. The PBM will Issue DoD appropriated funds (based on a letter of credit against a government account and authorized by the PBO) to pay for each TRICARE prescription, after receiving PBO's verification of the individual beneficiary's eligibility.

The filling of DaD beneficiary prescriptions at non-network retail pharmacies not

under contract to the PBM would not qualify as a DaD procurement through a

"centralized commodity management system." and therefore is not eligible for FCP.

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3. VA has always believed that implied in the statlte are the propositions that covered drugs purchased by the named Federal agencies at the statutory discount are not Intended to provide the Govemment or its contractors with an opportunity to make a profit at the expense of drug manufacturers and are not intended to offer commercial heahh care organizations access to Federal pricing indirectly through the diversion of the discounted drugs to them for use in the commercial maltel. TMA's TPBP satisfies these implied statutory policies through the wolt of the proposed CoD PBa using a sophisticated Phannacy Data Transaction System (POTS) that will, be linked to OEERS to ensure that non-DaD beneficiaries do not receive discounted prescriptions outside of TRICARE's parameters. The problem of possible diversion Is almost completely eliminated because the TPBP would never put actual discounted drugs In the hands of a retail pharmacy. The latter would merely use Its nonnal stocks of drugs, and CoD would receive the discount on the back end after Its PBO submits utilization data to the manufacturers. Also, TPBP is not properly described as an Insurance scheme because PBa software is used to approve prescriptions for every requesting beneficiary and DoO appropriated funds are used to pay for these prescriptions through PBM's efforts as agent of DoD. The only major difference between this model and the pharmaceutical supply contracUphannaceutlcal prime vendor models that VA and *DaD* use for their own hospitals is that, under the TPBP, DoO requests a discount in the form *ot* a rebate rather than up front at the time of the original purchase of the drug for the beneficiaries.

FACTUAL BACKGROUND:

Ever since CoD implemented its TRICARE program through the award of managed health care delivery contracts to civilian contractors for various regions of the United States In the mid-1990's, the office of CoD's Assistant Secretary for Health Affairs (OASHA) has been seeking to apply the pricing benefit of the P.L. to prescriptions fDled for beneficiaries by commercial subcontractors of the TRICARE contractor. After an exchange of correspondence with DoO's OGC and a lengthy discussion within VA OGC as to the appticability of the P.L. to prescriptions filled through retail pharmacies as part of a capitated managed health care contract that was not strictly cost based, VA OGC published on October 7, 1996. a "Dear Manufacturet' lettel containing guidance for manufacturers *of* covered drugs on several aspects of P.L. administration. The contents of the letter had been approved by the P.L. PoHcy Group.

Paragraph 3 of the letter to industry Informed manufacturers of the Interaction between VA and CoD concerning the possible eligibility of TRICARE contractors for FCPs. The MOear Manufacturer" letter then stated:

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-An exchange of infonnation between the OffICes of General Counsel
of DaD and VA has resulted In VA taking the position that the VHCA
[P.L.] does not require manufacturers to make FCPs available to the presently awarded TRICARE oontractors on orders placed by them or by their commercial pharmacy subcontractors for distribution through retail pharmacies. VA cannot conclude that such oovered drug purchases under the TRICARE program, as presently structured, constitute covered dl\lQ procurements by the DoD within the wording of the act. Major factors In this conclusion are the absence of any direct CoD payment for invoiced phannaceutlcal products and the lack of any way to trace pharmaceuticals purchased by a TRICARE contractor or subcontractor back to DaD on an Item-by-item basis:

DoD reacted to VA's "Dear Manufacturer-letter by proposing that legislation be enacted to amend Title 10 of the United Stated Code to specifically bring the procurement of

phannaceuticals on behalf of CoD by an authorized contractor through an authorized

retaU phannacy network or maN order program within the purview of 38 U.S.C. 8126.

This proposal was never enacted into law, apparently as a result of industry's hostility to

it when it was sent to Capitol Hill.

Subsequently, TMA, DaD O~C, and DoD OASHA representatives held discussions with
counterparts from VA to discuss how FCPs could be obtained for the increasingly large TRICARE retail phannacy expenditure. As an outgrowth of these discussions, TMA decided to carve the phannacy benefit oomponent out of its solicitations for the second round of regional TRICARE contracts and to create a CoD Pharmacy Benefit OffICe (PBO) that would be responsible for contracting with a commercial pharmacy benefttS management finn (PBM) (and, through It, with a retail phannacy network) which would serve as the PBO's agent for the procurement and dispensing of drugs for TRICARE beneficiaries outside of the military treatment facility system. This new approach was unveiled to VA In August 2001, and to industry In a general way at a pre-solicitation conference in September *2001.* A description of the proposal, along with a diagram, was included in a letter from TMA's General Counsel to VA's Assistant General Counsel (025) on September 17. 2001.

The new TRICARE Pharmacy Benefit Program (TPBP) was considered by the VA Public Law Policy Group at its 2001 annual meeting, but questions were raised which

required additional clarification. In November *2001,* 025 wrote to TMA's General

Counsel posing certain questions related to statutory Interpretation and the practical operation of the TPBP. TMA answered these questions on February 12, 2002, at a meeting on April 23, 2002, and in a follow-up letter of June 28, 2002.

On September 24,2002, the P.L. Policy Group reviewed all the correspondence and notes and concluded that TMA's interpretation of the P.L. as It applied to the TPBP was more reasonable than the opposing interpretation suggested by PhRMA.

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2005-G501-7 17

DELEGATIONS WITHIN VA:

When VA was in the process of Implementing the P.l. at the end of 1992 and the first half of 1993, there was a division of responsibUities. Since VHA's budget was the ultimate beneficiary of VA's participation In the statutory scheme, VHA's Drug and Pharmaceutical Product Management section (D&PPM) was given the responsibility of receiving and maintaining the annual reports of non-Federal Average Manufacturer Prices (Non-FAMP) for every covered drug that yield the FCPs for the following calendar year. On November 23, 1992, then Acting Secretary Principi signed a delegation to the Deputy Assistant Secretary for Acquisition and Materiel Management, giving him the authority to sign and administer Master and PhannaceuticaJ Pricing Agreements, with the authority to re-delegate as appropriate. On July 12. 2001, the Deputy Assistant Secretary for Acquisition and Materiel Management made a second re..<felegatlon or his authority to the Assistant Director, Pharmaceutical, Dental and Other Schedules, Federal Supply Schedule Service at the VA National Acquisition Center. This delegation superseded all previous delegations including the original one to the Chief, Pharmaceutical Products Division at the NAC.

On July 29, 1993, Deputy Secretary Gober signed a delegation document giving the authority to receive and rule on discretionary FCP Increase applications to an FCP Nomlnaf Increase Board consisting of anOGe attorney (025), Chief, Drugs and Pharmaceutical Products Management (119), and a VA *OIG* Audilor .chosen by the Director of Contract Audits (53C). Authority to hear and detennine appeals from an adverse decision of that Board was delegated to the VA Board of Contrad Appeals, whose decision shall be final. In the spirit of this delegation, the Public Law Policy Group was constituted by 025, the delegated administrative officials, and the OffIce of Inspedor General (53C) to meet at least annually and reach collegial resolution of significant issues of administration arising under the statute. The Policy Group has met in September or earty October of every year beginning In 1993 and has adopted almost all of its resolutions by consensus.

CONCLUSION:

For the above reasons, covered drugs purchased in the form of ODD beneficiary prescriptions under the retail portion of the new TPBP do qualify for Federal Ceiling Prices because, under the plan submitted to us, such purchases will be a procurement by DoD under a depot contracting system as defined In 38 U.S.C. 8126(h)(3).

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DEPARTMENT OF VETERANS AfrAJRS
Office of General Catinsel
PoSt Office Box 16
Hines IlSO'..'

December 30, 1992

Via Facsimile' U.S. Mail

In Reply Rele, To:

025

Dear Manufa.c:'turer:

We have received your request for an increase in the Federal ceiling price of yow: pha.:m4ceuti.cal product pursuant to the requirements of the Veterans Health Care Act of 1992 (the "Act"). The Act at 38 U.S.C~ 8126(a)(2) states that the price paid by the specified Federal agencies.....may nomJ.nally exceed the Federal ceiltng price (PCP) "if found by the Secretary to be in 1:he best intere,a of the Deparuaent or such Federal agencies.. VA has determined thAt, in most instances, the statutory teDI .~nnti ft~ 11y exceed" does not allow any increase that exceeds lD' of the IIIOst recently reported annual non-FAHP.

In order to initiAte the processing of A request for nominal increase in the Pederal ceiling price, a manufacturer muSt submit a. detailed. writ1:en request JUStifying the .increase for each separate Covered drug item and a certification by its President stating that the FcP is below the production cost of that covered drug and selling at that price would cause the manufacturer 1:0 lose money on ~ts overall business. The manufacturer also must: agree 't:O make - full disclosure of relevant company records 1:0 enable VA to verify the accuracy of the certification (see enclosed certification).

Shoula the Secreta%)' decide 1;0 grant t:.he ceiling price increAse, this amount vill be added to the FCP. If the addi.t.LQI1 of the nODtinal amount does not result in a posiuve

number, the ceiling price will be set At $.01. Thank you for your cooperat:ion with our efforts to l.mplement the new Ac.t. It you have any further guestions, please do not hesitate1:Q call (708) 216-2505.

Sincerely yours,

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~ -William E. Thomas, Jr.
Assistant General Counsel

6501-7

CEaTIFICATION

I, *I* (President of the company), hereby certify that: I am the .President of (the Ho.nufActw:er) *I* (adctresli) and that: I have the authority to execn1:e this cert:ificat:ion for, and on behalf of (lJanufaCturer). I certi£y that the current Federal ce.i.ling price of (fill in name of product) is below the cost,.of produc.i.ng this covered drug.

I certify that selling t:he Above covered,. drug product to the Department of Veterans A.ffaUa, Department: of Defense, and Public Health Service, including tb.e :r~tth'l\ Health Service at: t.bia price will cause (Kanufacturer) to loae money an its overAl.l busim!tsa. I fUrther Certify that (lfanufact:urer) I will make full disclosure of relevcnt financ.iAl records and that any representa1:ivea of the GoveDmlent shAJ.l have the right to f'1e and audit any anc1 all/recorda and relAted documents necessuy to verify the val.id.ity of my S1:41:e11ent:a.

S1.qnat:ure Date

Tit:le

Merck & Co., Inc.
P. O. Box 1000
North Wales, PA 19454

2005-G501-8

VIA E-mail and FAX

June 11, 2005

Mso Laurieann Duarte
General Services Administration
Regulatory Secretariat (VIR) 1800 F
Street, NoW., Room 4035
Washington, DoC. 20405

Re: GSAR Case No. 2005-G501

Dear Ms. Duarte:

Merck & Co., Inc. ("Merck") appreciates the opportunity to comment on the above-referenced issued in the April 12, 2005, *Federal Register.* Merck is one of the largest manufacturers and suppliers of pharmaceuticals to the Federal government, in particular to the Department of Defense and the Department of Veterans Affairs. Merck recognizes and greatly values the sacrifices and contributions of our service members and is committed to help assure that they and their families (and all Americans) have access to necessary medicines and the highest quality health care. Further, Merck is sensitive to the budgetary constraints cited as a basis for the Proposed Rule, but believes that the most effective means to control healthcare costs (to include drug prices) is the competitive marketplace, not price controls. Merck opposes the Proposed Rule because we do not believe that it is the best way to make high quality healthcare available to DoD beneficiaries and because we have concerns about its legal underpinnings and implementation challenges. Therefore, we urge GSA to withdraw the Proposed Rule.

Merck does not believe that the Proposed Rule is consistent with Congressional intent under Section 603 of the Veterans Healthcare Act ("VHCA"). The legislative history shows that Congress intended to extend the Federal Ceiling Prices ("FCP") authorized by VHCA to pharmaceuticals procured by government through only two types of procurements: Federal Supply Schedule ("FSS") contracts and depot contracts. Congress did not intend - and VHCA does not authorize - the extension of FCP to other types of procurements or to those purchases that arc not procurements, *e.g.*, reimbursements of prescription claims.

The Proposed Rule would establish a supplemental General Services Administration Regulation ("GSAR") concerning pharmacy benefit plans ("Federal Agency Retail Pharmacy Programs") of the "Big Four" agencies (V A, DoD, Public Health Service and the Coast Guard). Incorporation of the proposed supplemental GSAR into Federal Supply Classification ("FSC") Group 65 FSS contracts would require FSS holders (such as Merck) to pay "refunds" to the Big Four agencies on sales to beneficiaries of "covered drugs" dispensed through a qualifying Federal Agency Retail Pharmacy Program, collect and remit Industrial Funding Fees ("IFF") to V A, etc. Importantly, the transactions underlying the "refund" requirement are not procurements by a Big Four agency. Rather, the underlying transactions involve a retail pharmacy's purchase of a pharmaceutical product from a commercial source, followed by the sale of the product at a negotiated price to a beneficiary. Title passes from the commercial source to the retail pharmacy to the beneficiary; the Federal government never takes title or possession of the product. Federal dollars are introduced in the form ofre1mburscmcnts. Merck does not believe that the

2005-6501-8

retrospective introduction of federal dollars is sufficient to transfonn a commercial purchase into an authorized FSS order or creates a "virtual depot contracting system" to which Merck is a party.

A second defect with the Proposed Rule is that it appears to be outside GSA's statutory authority. Because V A is responsible for interpreting the VHCA, to the extent that the proposed rules involve substantive interpretation of the VHCA, V A (not GSA) should publish rules for notice and comment.

In addition, Merck believes that the Proposed Rule is ambiguous (which could cause significant operational difficulties) and imposes numerous additional record-keeping/reporting requirements. Ifthe Proposed Rule is not withdrawn, Merck respectfully requests that GSA clarify or reconsider several elements of the Proposed Rule, to include the following:

(1) Contract Modifications. The Proposed Rule is silent concerning the method by which the new clause would be incorporated into FSS contracts. FSS contracts include provisions stating that changes its tenns and conditions may be made changed only by written agreement of the parties. Merck requests GSA to clarify the Proposed Rule to reflect that modifications to current FSS contracts will require written agreement of the parties.

(2) Refund Calculations. Under the proposed clause, refunds would be calculated quarterly based on the difference between a benchmark price (either the actual sales price to the wholesaler or retail phannacy chain if known and auditable or the non-FAMP) and the FSS price or FCP, whichever is lower. However:

(a) The Proposed Rule does not specify whether the Federal agency or the contract holder would detennine the benchmark price to be used. Merck urges that this should be contract holder's decision, because the contract holder is in the best position to know the prices that it receives for its products from wholesalers or retail phannacy chains.

(b) The phrase "...if known and auditable..." is unclear as is the tenn "retail pharmacy chain." Merck respectfully requests clarification of these tenns.

(c) The Proposed Rule does not appear to address the importance of prospective identification of retail phannacies comprising the network phannacy. Such identification is essential so as to ensure that "refunds" are properly calculated (e.g., claims from ineligible phannacies, etc. are excluded).

(c) The proposed "refund" fonnula does not adjust potential differences between the package size (on which FCP is based) and the quantities of a covered drug that are considered in calculating the actual sales price (dispensed units, etc.).

(d) The Proposed Rule is unclear with regard to several aspects of non-F AMP calculations to include whether direct sales to retail phannacies may (or must) be included in non-F AMP calculations or whether utilization data may be handled in the non-FAMP calculation on a "cash" basis based on the date that a manufacturer pays a "refund."

(e) The Proposed Rule does not address the methodologies to be employed in situations where a product has been discontinued or when the patent covering a branded product has expired. With regard to the fonner, failure to synchronize multiple report dates could result in situations where the "refund" reporting period would extend beyond the period for which a non-F AMP was calculated.

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(f) The Proposed Rule contemplates that a Federal agency administering a retail pharmacy program would provide utilization flat file layout reports to FSS contract holders on the 15th day of the first month after the close of a calendar quarter. The manufacturer would then have 70 days to calculate the "refund" amount owed, reconcile the calculation with the Federal agency calculation, and pay the "refund." Thus, the refund amount would be due 85 days after the close of each calendar quarter.

Additionally, the proposed clause would require FSS contract holders to report retail pharmacy sales and pay the IFF within 60 days of the close of the quarter. At a minimum, the schedules in the two clauses should be reconciled so that IFF payments are not due on retail pharmacy sales until the later of 70 days after the contract holder's receipt of full utilization flat file layout reports or 85 days after the end of each calendar quarter.

(g) Disputes. The Proposed Rule would require the contract holder to pay the refund according to the agency's calculation (including the disputed amount) and then use "best good faith efforts" to resolve the dispute within 60 days. This approach is inconsistent with the Contracts Dispute Act and with best business practices. Merck urges revision of the dispute resolution process to include a requirement for good faith negotiations coupled with a manufacturer's payment of only that portion of the "refund" that is not disputed and to pay any balance plus interest by the due date of the next quarterly payment after the dispute is resolved. In addition, Merck urges revision of the dispute resolution process to impose similar obligations on Government parties [e.g., requiring remittance of IFF payments (with interest) or remittance of overpayments (with interest) if good faith negotiations or a court decision subsequently result in a reimbursement of part of the refund to the contractor].

The Proposed Rule seems to suggest that (a) a manufacturer's costs, time and effort required to comply with the Proposed Rule is minimal; and (b) there are no alternative mechanisms whereby DoD could decrease its pharmaceutical costs in the retail pharmacy sector. Merck respectfully disagrees with both of these suggestions. The effort required to calculate and pay "refunds" is not "essentially clerical"; rather, evaluating and processing of thousands of transactions in compliance with multiple statutes requires significant advanced professional skills and additional computer capability and capacity. Further, the business practices of the private sector - which include the use of pharmacy benefits managers and expanded use of mail-order pharmacies - are two of many cost-effective alternatives that are readily available. It is noteworthy that a mail-order pharmacy is an existing component ofDoD TRICARE health system, the TRICAREMail Order Pharmacy ("TMOP"). For TRICARE beneficiaries, TMOP is a cost-effective alternative to the retail pharmacy: a beneficiary pays $3, $9 or $22 cost-share for a 30-dav supply of drugs in the retail pharmacy setting; in contrast, a beneficiary pays the same $3, $9 or $22 costshare for a 90-day supply of drugs for purchases made from the TMOP.

Merck appreciates your consideration of these comments. We remain committed to working with DoD, V A and others in the Federal government to develop alternatives that can accommodate the concerns raised by all parties in a manner that is consistent with existing laws. As we strongly believe that the Proposed Rule is not authorized under law and would have detrimental policy and implementation consequences, we urge its withdrawal.

Sincerely,

/SI

C. E. Carty
Senior Attorney

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AMERICAN BAR ASSOCIATION

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June 13, 2005

Via E-Mail and First Class Mail

General Services Administration
Regulatory Secretariat (VIR)
1800 F Street, NW, Room 4035
ATTN: Ms. Laurieann Duarte
Washington, DC 20405

Re: **General Services Acquisition Regulation; Federal Agency Retail Pharmacy Program; 70 Fed. Reg. 19045 (April 12, 2005); GSAR Case 2005-G501**

Dear Ms. Duarte:

On behalf of the Section of Public Contract Law of the American Bar Association ("the Section"), I am submitting comments on the above-referenced matter. The Section consists of attorneys and associated professionals in private practice, industry, and government service. The Section's governing Council and substantive committees have members representing these three segments to ensure that all points of view are considered. By presenting their consensus view, the Section seeks to improve the process of public contracting for needed supplies, services, and public works.

The Section is authorized to submit comments on acquisition regulations under special authority granted by the Association's Board of Governors. The views expressed herein have not been approved by the House of Delegates or the Board of Governors of the American Bar Association and, therefore, should not be

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construed as representing the policy of the American Bar Association.[1]

I. INTRODUCTION

These comments are provided in response to the Proposed Rule entitled "Federal Agency Retail Pharmacy Program," issued by the General Services Administration ("GSA") on April 12, 2005. The rule includes a proposed contract clause that would be inserted in the Federal Supply Schedule ("FSS") contracts of manufacturers of pharmaceutical products listed on Schedule 65, Part I, Section B of the FSS. The proposed clause would allow certain government agencies to access Federal contract prices for pharmaceuticals through "refunds" on prescriptions filled by network retail pharmacies for government agency beneficiaries.[2] The proposed clause would be added to the General Services Acquisition Regulations ("GSAR").

Pursuant to the Veterans Health Care Act of 1992 ("VHCA"), the prices for covered drugs procured by the Federal agencies specified in the statute – that is, the Department of Defense ("DOD"), the Department of Veterans Affairs ("VA"), the Public Health Service ("PHS") and the Coast Guard – under "depot contracting systems or . . . Federal Supply Schedule ["FSS"]" contracts may not exceed the statutorily calculated Federal Ceiling Price ("FCP"). 38 U.S.C. §8126 (a)(2). Under the Proposed Rule, the government would be authorized to insert a clause into the FSS contracts of these particular contractors that would require them to "deem" orders for prescriptions, for pharmaceuticals purchased by Federal Agency Retail Pharmacy Program beneficiaries through participating retail pharmacies to be contract orders subject to the contract price, whether negotiated below FCP or capped at FCP. It specifically provides that a federal agency's "instruction to its contractor or subcontracted retail pharmacy to fill a prescription for a health care beneficiary of the agency . . . shall be deemed an order placed against [the FSS] contract."[3]

To qualify as a Federal Agency Retail Pharmacy Program, the program must be modeled after the TRICARE Retail Pharmacy ("TRRx") Program, a DOD entitlement program. The federal agency must be authorized to provide insurance

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[1] This letter is available in pdf format at http://www.abanet.org/contract/Federal/regscomm/home.html under the topic "Health Care."

[2] As you are aware, this issue does not relate to prices paid by Tri-Care beneficiaries and the Section does not take a position on any policy issue relating to prices paid by Tri-Care beneficiaries.

[3] 552.238-XX(c)(2); 70 Fed. Reg. 19050 (2005).

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type pharmacy benefits to individuals by reimbursing private sector pharmacies for prescriptions provided to the beneficiaries. In addition, the agency must enter into a contract with a fiscal intermediary called a pharmacy benefits manager ("PBM") under which the PBM agrees to provide a network of retail pharmacies with which they have payment agreements. Under the TRRx model, the PBM is paid a fee to administer the benefit (coverage, deductibles, cost shares) and, on behalf of the agency, reimburse the network retail pharmacies the agency's cost share of the pharmacies' prescription price with government funds (including non-appropriated Medicare funds) for all pharmacy sales of "covered drugs" dispensed to agency beneficiaries. The PBM is not a supplier and does not acquire or deliver any product. Accordingly, the parties to the prescription transaction are the beneficiary ordering the medication prescribed, the retail pharmacy providing the medication to the beneficiary, and the PBM acting as a government fiduciary and third party payer.

The Proposed Rule does not contemplate that the provider network pharmacy would be authorized to order contract line items under FSS contracts on behalf of an agency and invoice the agency or its fiscal intermediary at the FSS contract price. Rather, it contemplates that the units of drugs sold to the government beneficiaries would be taken from the retail pharmacy's commercial stock acquired from its usual commercial sources, rather than from government-owned property, and sold to the beneficiary at the commercial network price negotiated between the PBM and the pharmacy. The Proposed Rule also does not contemplate that the manufacturer have an agreement with the retail pharmacy authorizing it to distribute its products to the government or patients covered by a federal pharmacy benefit program. Consequently, in the reimbursement system covered by the Proposed Rule, there is no contract between the agency and the retail pharmacy authorizing it to act as a purchasing agent, nor is there a contract between the manufacturer and the retail pharmacy authorizing the pharmacy to take prescription orders under the manufacturer's FSS contract and sell prescriptions on its behalf.[4]

According to the Proposed Rule, the prescription units of covered drugs ordered through a retail pharmacy program would be "deemed" to be ordered by the federal agency from the manufacturer under an FSS contract through the retail pharmacy, thereby invoking FSS and FCP prices for these orders. The manufacturer would be required to refund to the federal agency the difference between a "benchmark" commercial price and the FSS contract price (FCP or the

[4] Only licensed pharmacies may fill prescription orders.

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negotiated FSS price for the drug, whichever is lower). The required contractor payment would not refund the difference between the FSS contract price and the price the pharmacy charged for the prescription or the share of the price the agency actually paid. The proposed clause would require manufacturers to treat retail pharmacy sales to beneficiaries as manufacturer sales and include them in their quarterly sales reports to VA and to pay the Industrial Funding Fee ("IFF") on those sales.

As explained in detail below, we believe that GSA has exceeded its rulemaking authority in undertaking the instant rulemaking. Specifically:

- The Federal Property and Administrative Services Act ("FPASA"), 40 U.S.C. § 501 and 41 U.S.C. § 259(b), does not confer authority on GSA to deem commercial orders as orders by an executive agency under an FSS contract;
- The VHCA does not confer rulemaking authority on GSA;
- The Federal Agency Retail Pharmacy Program extends beyond the statutory mandate of the VHCA.

We respectfully maintain that the Proposed Rule is an improper exercise of GSA's authority. Moreover, even if GSA were authorized to proceed with this rule, it would be necessary to revise the Proposed Rule to clarify certain implementation and operational aspects of the rebate program it seeks to create. For the reasons explained below, we urge GSA not to proceed with the Proposed Rule.

II. THE PROPOSED RULE EXCEEDS GSA'S AUTHORITY

To undertake a rulemaking, an agency must have authority to do so.[5] It is "a fundamental principle of administrative law that agencies may not self-levitate their power to promulgate regulations – they must rather find any such power in a source conferred by Congress."[6] In other words, there must be a "nexus between

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[5] *Chrysler Corp. v. Brown*, 441 U.S. 281, 303 (1979) (internal citations omitted).

[6] *Respect Inc. v. Comm. on Status of Women*, 815 F. Supp. 1112, 1123 (N.D. Ill. 1993) (court determined that the Department of Health and Human Services did not have authority to promulgate a regulation because the regulation in question was not within the contemplation of any existing statute).

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the regulation[] and some delegation of the requisite legislative authority by Congress."[7] To determine if the required nexus exists, we must "reasonably be able to conclude that [a] grant of authority [by Congress] contemplates the regulations issued."[8]

The "Introduction" and "Background" sections of the Proposed Rule point to two principal statutory bases of authority:

- Federal Property and Administrative Services Act ("FPASA"), 40 U.S.C. § 501 and 41 U.S.C. § 259(b)
- Veterans Health Care Act, 38 U.S.C. § 8126

As discussed below, these statutes do not contemplate that GSA (or any other agency) has the authority to "deem" an instruction by an agency, through a fiscal intermediary, to a retail pharmacy to dispense covered drugs to an agency beneficiary, to constitute an order by the agency under an FSS contract. Moreover, the Proposed Rule is inconsistent with the FAR.

A. The Federal Agency Retail Pharmacy Program Is Inconsistent With the Fundamental Elements of a Procurement

As discussed below, both statutes referenced in the Proposed Rule as possible sources of authority apply to federal procurements. Nevertheless, the relationships and transactions covered by the Proposed Rule do not involve a procurement by a federal agency as that term is used in federal jurisprudence. The meaning of the term "procurement" is well-established. A procurement is a transaction involving the acquisition of items or services for the use and benefit of the government.[9] Moreover, a fundamental principle of contract law requires privity of contract between the seller and the entity procuring the goods or services.[10] Another critical factor that separates procurements from other types of

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[7] *Chrysler Corp. v. Brown*, 441 U.S. 281, 304 (1979).

[8] *Liberty Mutual Ins. Co. v. Friedman*, 639 F.2d 164 (4th Cir. 1981) (citing *Chrysler Corp. v. Brown*, 441 U.S. 281, 308 (1979)).

[9] *See, e.g.*, 31 U.S.C. § 6303; FAR § 2.101 (defining acquisition as purchase or lease "the acquiring by contract . . . by and for the use of the Federal Government," and stating that "[a]cquisition begins at the point when agency needs are established . . . .").

[10] *See Etchey v. United States*, 15 Cl. Ct. 152, 154 (1988) (defining privity of contract as "that connection or relationship which [sic] exists between two or more contracting parties").

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transactions is that title must pass from the seller to the buyer.[11]

Not all Federal payments for goods and services are procurements. Federal agencies do have inherent power to procure supplies such as pharmaceuticals for their own use in carrying out government functions, although that inherent power may be limited by procurement laws and regulations. By statute, and as discussed below, GSA has special authority to procure supplies for the use of other agencies. By contrast, agencies have no inherent power to use tax dollars for the assistance of non-governmental entities (including members of the public as such beneficiaries), whether directly or by paying for supplies provided to beneficiaries. These assistance expenditures must be specifically authorized by Congress[12]. Where the purpose of the transaction is to transfer something of value to a recipient in order to carry out a public purpose of support or stimulation authorized by a law of the United States, the vehicle is a grant -- which requires specific legislative authorization -- and not a contract.[13] Under the Federal Agency Retail Pharmacy Programs described in the Proposed Rule, the purpose of the federal payments to retail pharmacies for prescribed medication is to provide assistance to members of the public, i.e., to ensure that medication is provided to federal beneficiaries. These payments are not made in order to obtain supplies of drugs for the direct use and benefit of DOD. Accordingly, these transactions are not procurements and GSA may not treat them as federal agency orders under the FSS contracts.

A Federal Agency Retail Pharmacy Program, as described in the Proposed Rule, involves a third-party reimbursement system through which a contracted fiscal intermediary (the PBM) reimburses retail pharmacies for prescriptions provided to beneficiaries. Commercial packages of drugs are purchased by retail pharmacies through commercial distribution channels without any federal agency direction, involvement, or control. The only involvement by the government in these transactions is to approve the eligibility of the federal health plan beneficiary, thereby authorizing its PBM contractor to reimburse the pharmacy the government's cost-share for the dispensed medication with federal funds. There is no contract between the manufacturer and the government providing any particular price – FCP, FSS, or otherwise – for the federal reimbursements provided to the retail pharmacies. Moreover, as noted, the orders are placed by, and for the use of,

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[11] *See, e.g.,* Uniform Commercial Code § 2-106(1) (defining a sale as "passing of title from the seller to a buyer for a price . . . .").

[12] General Accounting Office, *Principles of Federal Appropriations Law*, 10-11 (2d ed. 1992)

[13] 31 U.S.C. 6303-6305

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the beneficiaries. In short, the government payments to the retail pharmacies are insurance benefit payments in the form of cost-sharing subsidies. Laws and regulations governing federal procurement distinguish such transactions as "nonprocurement transactions." *See, e.g.*, FAR 9.403 (examples of non-procurement transactions include grants, cooperative agreements, subsidies, insurance, and payments for specified use).

In January 2004, the Section submitted comments to Dr. William Winkenwerder Jr., Assistant Secretary of Defense, Health Affairs, expressing the Section's view that TRRx transactions between retail pharmacies and TRICARE beneficiaries do not constitute the acquisition of supplies under Federal procurement laws and regulations. Because the Section's comments are enclosed, detailed discussion of those points is unnecessary. In summary, the Section's conclusion was based on the following rationale:

(1) Title to dispensed covered drugs will never pass to the federal government, as required by the FAR and by the Uniform Commercial Code for a sale and purchase to occur;

(2) Not all payments received by the retail pharmacies for the covered drugs dispensed to TRICARE beneficiaries will involve appropriated funds, as is required for a federal procurement;

(3) The covered drugs dispensed by a retail pharmacy to the TRICARE beneficiaries will not necessarily match any package size listed as a line item in FSS contracts (e.g., SKU or NDC);

(4) The covered drugs dispensed by a retail pharmacy to the TRICARE beneficiary will not be traceable to any order issued by a contracting officer; and

(5) The retail pharmacies are not acting as the agent of the Federal government when purchasing the covered drugs from commercial wholesalers.

Because the Proposed Rule applies to commercial transactions occurring between federal agency beneficiaries and a retail pharmacy, the Section's January 2004 comments outlined above also apply to the Proposed Rule.

The Proposed Rule describes this instruction by the federal agency to fill a beneficiary's prescription as a "deemed order" under the FSS that would generate a refund. Calling these instructions "deemed orders," however, cannot transform

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them into government orders under the FSS contract in view of the fact that the drugs actually are procured by retail pharmacies. In fact, the Proposed Rule concedes that a federal agency will never place an order for the drugs dispensed by a retail pharmacy to a TRICARE beneficiary directly or by the retail pharmacy acting as an authorized purchasing agent. To overcome the lack of privity of contract, the Proposed Rule provides that "[t]he drugs will be *deemed* to have been ordered by the Federal agency through the FSS contract, for the purposes of establishing price, delivery, and scope of coverage . . .."[14] The Proposed Rule resorts to "deemed" orders because there are no actual orders by a federal agency under a Federal Agency Retail Pharmacy Program.

Further, the Proposed Rule does not identify any statutory or other basis for authorizing non-governmental entities to place FSS orders on behalf of the government in the absence of a contract establishing that agency relationship. Nor does it attempt to rely on FAR Part 51,[15] which describes the mechanism for authorizing cost-reimbursement contractors to access FSS contracts. This is not surprising given that retail pharmacies – regardless of their participation within a commercial PBM network – and federal health care plan beneficiaries are not cost reimbursement contractors of the federal government. Because the retail pharmacies through which the agencies are ostensibly procuring the dispensed drugs are not authorized to order drugs on behalf of the government directly under the manufacturers' FSS contracts, the manufacturers cannot by rule be "deemed" responsible for refunding a portion of the government's expenditure on these transactions.

Likewise, the proposed method of invoicing and paying manufacturers for these drugs further exemplifies how the Proposed Rule departs from fundamental procurement norms. One of the standard aspects of a procurement relationship is that the contracting officer will be privy to the payment terms of the contract. Under the Proposed Rule, "[t]he time and method of payments to the Contractor for FSS items . . . *will be determined in accordance to commercial agreements between the FSS Contractor and such pharmacies or their authorized Pharmaceutical prime vendor.*"[16] Therefore, because the Proposed Rule

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[14] 552.238-XX(b); 70 Fed. Reg. 19050 (2005) (emphasis added).

[15] Generally, FAR Part 51 provides that "Before issuing an authorization to a contractor to use Government supply sources ..., the contracting officer shall place in the contract file a written finding supporting issuance of the authorization." FAR 51.102(a).

[16] 552.238-XX(d); 70 Fed. Reg. 19050 (2005) (emphasis added).

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acknowledges that transactions actually occur pursuant to private commercial contracts rather than pursuant to orders placed under FSS contracts, the provisions containing the time and method of payment under those private commercial contracts appear to be incorporated by reference into the FSS contracts. A federal contracting officer will never review, approve, or know the substance of such payment terms. Moreover, some of the transactions targeted by the Proposed Rule may involve multiple contractual relationships reflecting a chain of wholesalers, distributors, or other resellers, some of which will not have direct contracts with the FSS contractor.

In sum, the transactions required under Federal Agency Pharmacy Programs described in the Proposed Rule reflect the payment of subsidies to reimburse commercial health care providers for drugs obtained through normal commercial distribution channels without any privity of contract with the federal government. Due to the missing contractual link between the government and the manufacturer and the absence of a procurement action, there is no price agreement between those parties. In addition, the Proposed Rule requires rebates (referred to as "refunds") applied to the price ultimately paid (through its PBM contractor) to reduce the net benefit outlay, but payment of these rebates by the FSS contractors never results in the actual FSS contract price. The procurement gymnastics required to make this clause functional demonstrate that the Proposed Rule is outside the bounds of GSA's statutory authority.

B. The Federal Property And Administrative Services Act Does Not Confer Authority On GSA To Deem Commercial Orders As Orders By An Executive Agency Under An FSS Contract

The Introduction to the Proposed Rule incorrectly cites to FPASA as authority for the rulemaking action being taken by GSA. FPASA sets forth procedures relating to GSA's procurement of goods and services for executive agency use. As discussed above, procurement contracts authorized by FPASA may not be used as a vehicle for non-procurement transactions in order that beneficiaries may obtain drugs subsidized with federal dollars at federal contract prices. Further, FPASA does not authorize, or even contemplate, a scheme where the items being procured are not acquired from a government source of supply (such as an FSS contract or depot) as a procurement. Because the "covered drugs" dispensed through a Federal Agency Retail Pharmacy Program would be acquired through commercial agreements to which the government is not a party, FPASA does not

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authorize GSA to impose the Proposed Rule.[17]

1. FPASA Does Not Authorize Procurements Through Commercial Third Parties

Section 201(a) of FPASA, 40 U.S.C. § 501, authorizes GSA to "procure and supply personal property and nonpersonal services for executive agencies to use in the proper discharge of their responsibilities."[18] The purpose of FPASA is "to provide the Federal government with an economical and efficient system for . . . procuring and supplying property and nonpersonal services."[19] Specifically, Congress intended to empower GSA "to regulate the policies and methods of executive agencies with respect to the procurement and supply of personal property and nonpersonal services."[20] FPASA defines the term "procurement" to mean "all stages of the process of acquiring property or services, beginning with the process for determining a need for property or services and ending with contract completion and closeout."[21]

Section 309 of FPASA, 41 U.S.C. § 259(b), the other FPASA provision cited in the Proposed Rule, includes procedures established by GSA for the award of multiple award schedule contracts within the definition of "competitive procedures" under the statute if participation in the multiple award program is "open to all responsible sources" and contracts awarded through the GSA procedures result in "the lowest cost alternative to meet the needs of the Government."[22] Section 259(b) is a definitional provision. It provides that "competitive procedures" are those procedures under which an "executive agency" enters into a contract pursuant to full and open competition, and may include

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[17] The proposed GSAR clause also fails to meet FAR 1.302(b) because it would not further the needs of GSA (the agency promulgating the regulation). Instead, by its terms, the clause would benefit only the VA, DOD, PHS, and Coast Guard by entitling them to recover refunds on third party transactions. *See Service Employees Int'l Union v. Gen'l Servs. Admin.*, 830 F. Supp. 5, 9-10 (D.D.C. 1993) (GSA supplemental regulation held improper because it was contrary to a FAR clause and did not address a specific GSA need).

[18] 40 U.S.C. § 501(b)(1)(A).

[19] 40 U.S.C. § 471.

[20] H.R.Rep. No. 670, 81st Cong., 1st Sess. (1949), reprinted in 1949 U.S. Code Cong. & Ad.News 1475 (emphasis added).

[21] 41 U.S.C. § 403.

[22] 41 U.S.C. § 259(b).

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procedures relating to the award of multiple award schedule contracts.[23]

Neither of the two cited FPASA provisions (nor any other FPASA provision) allows the addition/modification to the FSS contracts described in Proposed Rule. For example, neither provision contemplates the establishment of procedures under which a purely commercial enterprise, which is not party to a procurement contract with the government, such as the retail pharmacies in the Proposed Rule, may be deemed to have ordered property or services from an FSS contractor on behalf of the government for purposes of accessing the pricing, ordering, and delivery terms of an FSS contract. As noted, FPASA authorizes GSA to establish procedures that govern the actual procurement of property and services for use by executive agencies. FPASA does not support a scheme whereby an instruction from a federal agency to a retail pharmacy authorizing payment for a beneficiary prescription order could serve as a substitute for an order by an authorized entity under the FSS contract.

2. A "Deemed Order" Is Not Contemplated by FPASA

Consistent with the limitations of its authority under FPASA and other statutes, GSA issued GSA Order ADM 4800.2E ("GSA Order") that identifies those entities and organizations that are eligible to order supplies and services from FSS contracts. In the GSA Order, GSA notes that FPASA authorizes it to "procure and supply personal property and non-personal services for executive agencies and other Federal agencies, mixed-ownership Government corporations as identified in the Government Corporation Control Act, the District of Columbia, and qualified nonprofit agencies for the blind or other severely handicapped for use in making or providing an approved commodity or service to the Government."[24]

As discussed, in the scheme contemplated by the Proposed Rule, the drugs are ordered by the beneficiaries. That is, prescription doses of the drugs are ordered from the retail pharmacy by the beneficiary, based on the beneficiary's prescription received from its physician, and payment of the agency's cost share is authorized by the agency's fiscal intermediary at the point of sale. The drugs that are dispensed are procured by commercial retail pharmacies through commercial transactions to which the government is not a party. The drugs themselves are not ordered by any executive agency from the FSS contracts, but rather are ordered by a beneficiary and filled from the retail pharmacy's commercial inventory.

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[23] 41 U.S.C. § 259(b).

[24] GSA Order ¶ 3.

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The limits of the GSA Order are consistent with our conclusion that GSA lacks authority to "deem" prescription orders to be agency orders under the FSS contracts. The GSA Order specifically limits the entities that may order from the FSS contracts to executive agencies and other organizations that have explicit statutory or regulatory authority to access government sources of supply. Moreover, although contractors that have cost reimbursement contracts are permitted in certain circumstances to access FSS contracts, manufacturers are not required to accept all such orders.[25] The Proposed Rule conflicts with the GSA Order because it would allow drugs that are procured by entities other than an executive agency to be deemed "ordered" by an executive agency under FSS contracts. There is no statutory authority to issue a regulation of such expansive scope.

Finally, the introduction of the "deemed order" concept could have unintended and significant consequences to the GSA schedule program. FSS contracts were intended to provide an efficient means for executive agencies to procure products and services for their own use. Permitting deemed orders such as those contemplated in the Proposed Rule would expand the FSS contracts far beyond their intended scope. It also could set a broad precedent for purely commercial orders to be deemed orders under other FSS contracts. Such a precedent could undermine the economics and integrity of the FSS contracting system, and discourage contractor participation in the program.

3. The GSAR Impermissibly Conflicts with the FAR

The GSAR may supplement, but not conflict with, the Federal Acquisition Regulation. The "deemed order" concept of the Proposed Rule, however, conflicts directly with the ordering requirements set forth in FAR 8.406-1 ("Order Placement"), which provides that an "ordering activity shall place an order *directly* with the contractor in accordance with the terms and conditions of the pricelists" and specifies the terms that must be included in the order. (Emphasis added.) Under the Proposed Rule, no order is placed "directly" with the contractor, either by the agency or by an ordering agent under contract with the agency. Because the proposed GSAR clause conflicts with the FAR (and no deviation from the FAR is being sought), the proposed clause is an invalid exercise of agency authority. In addition, the GSAR conflicts with FAR 8.402, which requires the pricing and terms and conditions for contract items ordered from the schedule contractor. The deemed orders are for prescription unit doses, not the package units (and related

[25] *See* I-FSS-103, Scope of Contract – Worldwide (JULY 2002) (VARIATION).

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prices) listed on the FSS contract. Finally, the Proposed Rule conflicts with FAR 12.301(b) and 52.212-4(n), which govern the terms and conditions in contracts for commercial items (including FSS Schedule 65) and specifically require title to items furnished under the contract to pass to the government. Under the Proposed Rule, title for drugs furnished under the contract ostensibly through retail pharmacies pursuant to "deemed" orders would never pass to the agency deemed to be ordering the contract items. For all these reasons, the GSAR is an invalid exercise of GSA authority.

C. The Veterans Health Care Act Does Not Authorize the Proposed Rule

In addition to the references to the FPASA in the "Introduction" to the Proposed Rule as providing authority for the rulemaking, there are a number of references to Section 603 of the Veterans Health Care Act of 1992 ("the VHCA"), 38 U.S.C. § 8126, in the "Background" section of the Proposed Rule. These references, which were included to demonstrate that the VHCA provides independent statutory authority for the Proposed Rule, cannot and do not serve this purpose. As discussed below, the VHCA establishes a pricing program that places upper limits on the prices of drugs procured by certain federal agencies under FSS and depot contracts. It does not entitle federal agencies to refunds based on retail sales that are reimbursed through federal health insurance programs.

1. The VHCA is a Pricing Statute Administered by the VA

The VHCA establishes a federal pricing program administered by the VA. Participation in the program is required in order for a company's products to be paid for with federal funds in several contexts – including the Medicaid program.[26] To participate, a manufacturer must execute a Master Agreement and Pharmaceutical Pricing Agreement with the VA in which it commits to make its "covered drugs" available on FSS contracts. The manufacturer further agrees that prices charged certain federal agencies, including DOD, VA, PHS, and the Coast Guard (the "Big 4") on FSS contracts and depot contracts cannot exceed Federal Ceiling Prices (FCPs").[27]

As is evident from the basic terms of the statute, the only impact that the

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[26] 38 U.S.C. § 8126(a).

[27] *Id.* *See* 38 U.S.C. § 8126(e)(3).

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VHCA can have on FSS contracts is to create caps on prices offered on these contracts. 38 U.S.C. § 8126(a)(2). Accordingly, the VHCA cannot properly be considered to authorize efforts to modify non-price terms of FSS contracts such as the ordering provisions by requiring contractors to treat "deemed orders" by retail pharmacies as purchases under the contract.

Moreover, in view of the fact that the VA is the sole agency empowered to interpret and apply the requirements of the VHCA, it would be inappropriate for GSA to rely on the statute as authority for its Proposed Rule. Recognizing this delineation of authority, DOD has posted the following question and answer on its TRICARE web site:

> ...Is there a letter from GSA approving [the TRRx] program?
>
> ***Response: No, GSA does not have jurisdiction over TRICARE or the application of Federal ceiling prices to TRRx under P.L. 102-585, Sect. 603.***[28]

Accordingly, GSA may not rely on the VHCA as providing a statutory basis for the Proposed Rule.

2. VHCA Federal Ceiling Prices Only Apply To "Procurements"

The VHCA places upper limits on the prices that may be charged under two types of federal procurement contracts: FSS contracts and depot contracts. In the Proposed Rule, GSA indicates that the new FSS clause would apply "for those Federal Agency Retail Pharmacy Programs . . . determined by the VA Secretary to qualify as [VHCA] 'depot' contracting system[s]...."[29] As provided below, however, the Federal Agency Retail Pharmacy Programs described in the Proposed Rule simply do not meet the VHCA's definition of "depot."

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[28] *See* Q&A Pages re: TRRx on TRICARE website posted Oct. 28, 2004, answering questions raised at May 11, 2004 Industry Conference re: TRRx (http://www.tricare.osd.mil/pharm_mfg/downloads/FederalPricingForumQuesAns_Final.pdf) (P.L. 102-585 is the VHCA, codified in relevant part at 38 U.S.C. § 8126).

[29] 69 Fed. Reg. at 19406 (the Proposed Rule provides that the clause should be added to FSS contracts as set forth in 38 U.S.C. 8126). The VA previously made such determination regarding the TRICARE Retail Pharmacy Program (TRRx) in a form letter to manufacturers of covered drugs. *See* Dear Manufacturer Letter, dated October 14, 2004 (http://www1.va.gov/oamm/nac/fsss/files/20041014DearManufacturer.pdf).

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The term "depot" is defined under the VHCA as:

> A centralized commodity management system through which covered drugs procured by an agency of the Federal Government are –
>
> (A) received, stored, and delivered through –
>
> (i) a Federally owned and operated warehouse system, or
> (ii) a commercial entity operating under contract with such agency; or
>
> (B) delivered directly from the commercial source to the entity using such covered drugs.

Following enactment of the VHCA, the VA elaborated on its understanding of the term depot, describing it as a "centralized commodity management system[] through which covered drugs are: (A) received, stored and delivered to a listed Federal agency through a Federally-owned warehouse system or a commercial warehouse system operating under contract with the *procuring* Federal agency; or (B) delivered directly from the manufacturer or its agent to a listed Federal agency's ordering activity at its purchasing address."[30]

As is clear from the statutory definition and the VA's own interpretation of the term, for a commodity management system to qualify as a depot under the VHCA, the government must necessarily "procure" drugs from a manufacturer.

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[30] Letter from P. Anderson, Assistant General Counsel of the VA, to R. Seaman, General Counsel of TRICARE Management Activity, dated November 1, 2001 (emphasis added) (discussing 1994 VA interpretation of the term depot).

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a. A Separate VA Rulemaking is Required In Connection With Any Conclusion That a Pharmacy Program Constitutes a VHCA Depot

As an initial point, even if there were a legal basis for concluding that the Federal Agency Retail Pharmacy Programs described in the Proposed Rule could be considered a procurement and thus meet the VHCA depot definition, any such determination would have to result from a rulemaking process. Notice and comment rulemaking is required where an agency determination involves a substantive interpretation of a statute.[31] A conclusion that a retail pharmacy program meets the VHCA definition of the term "depot" would necessarily require a substantive determination under the VHCA.[32]

Thus far, the VA has deemed one Federal Agency Retail Pharmacy Program– the TRICARE Retail Pharmacy Program ("TRRx") – to be a depot under the VHCA. Nevertheless, the VA has not engaged in notice and comment rulemaking in connection with this determination; rather, it has issued a "Dear Manufacturer Letter" to industry stating its conclusion that TRRx constitutes a VHCA depot.[33] To the extent that GSA is relying on the VA determination published in the VA's letter that TRRx is a depot for which rebates would be triggered under its new FSS clause, such reliance is misplaced given that the letter does not meet the standard notice and comment requirements. Moreover, given that GSA is not authorized to interpret the VHCA, the instant Proposed Rule cannot be considered to satisfy the rulemaking requirement with respect to whether any Federal Agency Retail Program meets the VHCA definition of depot. Rather, a separate VA rulemaking specifically addressing the depot determination would be required prior to the implementation of any requirement to pay refunds under the FSS clause in the Proposed Rule.

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[31] *See* 5 U.S.C. § 553.

[32] Moreover, such determination would necessarily involve the interpretation of "procurement policy [or] procedure . . . relating to the expenditure of appropriated funds" that would have a significant *cost impact* on contractors. *See* 41 U.S.C. § 418b (emphasis added) (requiring rulemaking under such circumstances).

[33] *See* Dear Manufacturer Letter, dated October 14, 2004 (http://www1.va.gov/oamm/nac/fsss/files/20041014DearManufacturer.pdf).

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b. Federal Agency Retail Pharmacy Programs Cannot Be Considered VHCA Depots Because They Do Not Involve Procurements

The VHCA definition of "depot" involves a centralized commodity management system through which drugs are *procured* by a federal agency. As described above, Federal Agency Retail Pharmacy Programs as described in the Proposed Rule do not involve procurements by the government. Rather, they involve third-party reimbursement systems through which a contracted fiscal intermediary (the PBM) reimburses retail pharmacies for prescriptions provided to beneficiaries. These programs involve the purchase of drugs by pharmacies through commercial distribution channels. Later, when a prescription order is placed, the government determines the eligibility of the federal health plan beneficiary, and can authorize its PBM contractor to reimburse the pharmacy the government's cost-share for the dispensed medication with federal funds. There is no contract between the manufacturer and the government providing any particular price – FCP, FSS, or otherwise – for these transactions. Prescription orders are placed by health plan beneficiaries when they submit their prescriptions. The drugs obtained clearly are for the use of these beneficiaries – and not the government. After the prescription is dispensed, the federal agency reimburses the retail pharmacy, as is the standard procedure under insurance benefit payment systems that involve cost-sharing between the insurer and the beneficiary.

In sum, the elaborate web of transactions among four distinct entities – the retail pharmacy, the federal health plan beneficiary, the PBM, and the federal agency – cannot be considered to "add up" to a federal procurement. As discussed above, a procurement is a transaction involving the acquisition of items or services for the use and benefit of the government. Procurements involve privity of contract between the seller and the buyer and the passing of title between these entities. They involve orders by the government and payment of contractor invoices by the government. None of these criteria that are fundamental to procurement transactions are present in Federal Agency Retail Pharmacy Programs.

c. Federal Agency Retail Pharmacy Programs are Not Centralized Commodity Management Systems

Moreover, apart from the fact that they do not involve federal procurements, Federal Agency Retail Pharmacy Programs as described in the Proposed Rule do not involve centralized commodity management systems, as is contemplated in the VHCA definition of depot. As provided above, a commodity management system involves a system where drugs are: "(A) received, stored and delivered to a listed

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federal agency through a Federally-owned warehouse system or a commercial warehouse system operating under contract with the *procuring* Federal agency; or (B) delivered directly from the manufacturer or its agent to a listed Federal agency's ordering activity at its purchasing address."[34] These arrangements involve contractual relationships that establish a distribution chain through which drugs sold by a manufacturer are delivered through a third party to a federal purchaser. At a minimum, there is a purchase contract between the manufacturer selling product and the federal customer and a distribution agreement between the manufacturer and an intermediary that delivers the product to federal customers. One established example of such commodity management system that constitutes a VHCA depot is the VA's prime vendor program, which involves a separate agreement between the VA and one or more wholesalers under which the wholesaler purchases, delivers, and invoices for orders under manufacturer's FSS contracts. The prime vendor(s) provides these services on behalf of the government in connection with the established FSS contractors between manufacturers and the VA.

In an attempt to meet the VHCA depot definition, the Proposed Rule appears to rely on a fiction that retail pharmacies are procuring drugs as purchasing agents of the government. The Proposed Rule itself, however, does not identify any statutory or other basis for authorizing these commercial entities to place FSS orders on behalf of the government. Despite the proposed FSS clause's reference to "a Federal agency's directly contracted or indirectly subcontracted retail pharmacy" (*see* Rule at (e)(4)), there is no agreement between the government and any Federal Agency Retail Pharmacy Program network pharmacy that would create any contractual or subcontractual relationship between the two entities.

It would seem that the agreements the government is referencing here are the network retail pharmacies' arrangements with the Federal Agency Retail Pharmacy Program PBM. As noted above, the PBM serves under contract with the government as the fiscal intermediary under the Federal Agency Retail Pharmacy Program. The PBM's function under the contract is to reimburse pharmacies that dispense drugs to federal beneficiaries; it is not a purchaser of drugs. The agreements between the PBM and its network retail pharmacies simply permit the PBM to provide the pharmacies a particular retail prescription reimbursement price for drug prescriptions dispensed to the PBM's client's plan members – here the

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[34] Letter from P. Anderson, Assistant General Counsel of the VA, to R. Seaman, General Counsel of TRICARE Management Activity, dated November 1, 2001 (emphasis added) (discussing 1994 VA interpretation of the term depot).

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client is the federal health plan – e.g., TRRx. Given that these agreements have no relationship to the actual retail pharmacy drug procurement transactions, they cannot be considered to create an agency relationship between the federal government and network retail pharmacies such that the retail pharmacies drug purchases would somehow be linked up with the a federal contract allowing the purchase of drugs from a manufacturer.

In addition, as noted above, given that the PBM's network retail pharmacies are not contractually linked to the government in any way, and that the government is not procuring drugs under these Federal Agency Retail Pharmacy Programs, there is no basis for any assertion that the pharmacies could be authorized to access FSS contracts as cost reimbursement contractors of the government under FAR Part 51.[35] As can be seen, contractual relationships that would be required in order to establish a commodity management system as contemplated under the VHCA definition of the term depot simply do not exist under the types of Federal Agency Retail Pharmacy Programs described in the Proposed Rule.

3. The VHCA Does Not Require A Manufacturer To Provide FSS Pricing under Depot Arrangements

As discussed above, the Federal Agency Retail Pharmacy Programs discussed in the Proposed Rule are health insurance reimbursement programs that cannot properly be considered depot contracts as that term is defined in the VHCA. Nevertheless, even if a Federal Agency Retail Program could meet the depot definition as described in the VHCA, the statute only places a cap on the pricing offered to the designated agencies, but does not authorize the VA, GSA, or any other agency to require manufacturers to offer FSS pricing on depot contracts.

As noted, the VHCA imposes price caps (FCPs) on two distinct types of contracts – FSS contracts and depot contracts. It does not, however, mandate the actual pricing on these contracts. Moreover, it does not mandate that the pricing on a manufacturer's depot contract with the government be the same as its FSS contract pricing. Given that these two types of arrangements are separately negotiated and priced, it is quite possible that a manufacturer will provide pricing on its FSS contract that is different from that offered on its depot contract.

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[35] Generally, FAR Part 51 provides that "Before issuing an authorization to a contractor to use Government supply sources ..., the contracting officer shall place in the contract file a written finding supporting issuance of the authorization." FAR 51.102(a).

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For example, a manufacturer may negotiate pricing that is lower than applicable FCPs on its FSS contract, while it makes FCPs available on separate depot contracts.[36] The reverse could also be the case, with subceiling pricing being made available on a depot contract and FCP-based pricing made available on a company's FSS contract. Nevertheless, to the extent that a manufacturer chooses to make such sub-ceiling pricing available, it does so voluntarily and only on the terms specified under the particular contract. Thus, if a manufacturer offers sub-ceiling pricing on its FSS contract, it may not be required to provide that same sub-ceiling pricing on a depot contract that it might enter into with the government. The VA has recognizes that agreement by pharmaceutical companies is required before applying FSS contract pricing under depot arrangements. It is for this reason that the VA includes a clause in its FSS contracts permitting, but not requiring, participation in its prime vendor program (described above), which is considered a commodity management system that meets the depot definition. Without a manufacturer's participation in the program, federal purchasers simply are not permitted to access FSS pricing through the prime vendor arrangements.

Yet, under the Proposed Rule, retail pharmacy programs that are determined to be VHCA depots would automatically be entitled access to FSS pricing. Conceptually, the Proposed Rule superimposes these "depots" onto different contract vehicles – FSS contracts – by considering dispensed units to be "deemed orders" under those contracts. Even if it were otherwise permissible to consider retail pharmacy reimbursement transactions as FSS contract orders, the VHCA simply does not authorize the government to require a contractor to merge its depot and FSS contract vehicles such that FSS pricing will be applied to their depot contracts. Unless a manufacturer voluntarily agrees to offer FSS pricing on a depot contract, it may not be forced to do so. Mandating FSS pricing on depot contracts runs afoul of basic contracting and procurement principles that require agreement on price by the contracting party and the government.

III. THE PROPOSED RULE SHOULD BE CLARIFIED

Even if, contrary to the legal principles discussed above, it were determined that the Proposed Rule does not exceed GSA's authority, the Rule raises a number of additional procurement-related issues that require clarification, as discussed below.

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[36] *See* 70 Fed. Reg. at 19050 (acknowledging that the FSS price for a drug can be lower than the applicable FCP).

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A. It Is Unclear How The Proposed Rule Will Be Implemented

The Proposed Rule provides in 538.XX02 that "the contracting officer shall insert the clause... in solicitation and schedule contracts for Schedule 65, Part I." Although it is clear that the VA may insert the new clause in future FSS solicitations, the VA may not incorporate the clause into a current FSS contract that has already been executed. FAR 52.212-4(c) requires a bilateral written agreement for changes in the terms and conditions of a commercial item procurement, such as the FSS contract for pharmaceuticals. Accordingly, if the government unilaterally were to amend existing FSS contracts to incorporate the Federal Agency Retail Pharmacy Program clause without negotiating with the contractor and providing consideration for the modification, that action would constitute a breach of contract.[37] GSA should modify the Proposed Rule to make clear that the clause will not be unilaterally added to existing FSS contracts.

B. Disputes

In 552.238-XX(h)(2), the Proposed Rule would require the parties, in the event of a dispute over the amount of a refund, to engage in "best good faith" negotiations for a 60 day period before the contractor may file a claim. Although the Contract Disputes Act ("CDA") encourages alternative dispute resolution ("ADR"), the CDA does not permit mandatory negotiations and exhaustion requirements of this nature. Additionally, even if the CDA authorized a mandatory negotiation provision, the clause in subsection 552.238-XX (h)(3) does not provide any guidance to contractors in the event that the negotiations do not resolve the disagreement. The clause should be modified to require the contractor to redress any disputes through the Disputes Clause of the FSS contracts. Consistent with the CDA, the clause could be modified to add a voluntary negotiation or ADR process, but could not require the parties to pursue that process as a substitute for the process mandated by the CDA.

C. The IFF Payment Should Not Be Available for Deemed Orders

Subsection 552.238-XX(i) of the clause would require FSS contractors to remit the Industrial Funding Fee ("IFF") for retail pharmacy sales in accordance with the timelines and procedures established in 552.238-74 ("Industrial Funding

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[37] FAR 52.212-4(c), FAR 43.103. *See, e.g., United States v. Winstar Corp.*, 518 U.S. 839 (1996) (holding that government enactment of a statute that adversely affected a party's contract rights constituted a breach of contract).

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Fees and Sales Reporting (JUL 2003) (VARIATION)"). In our view, requiring FSS contractors to pay the Industrial Funding Fees on retail pharmacy sales (to which the FSS contractor is not a party) would be inappropriate. The purpose of an IFF payment is to fund VA's administration of the FSS contract. For retail pharmacy sales, however, the FSS contracts are not implicated and VA has no administrative role. Accordingly, payment of the IFF for such "deemed orders" would be unrelated to any service that VA provides and thus would be unnecessary.

Moreover, the IFF and Sales Reporting clause provides that, in reporting sales, "the dollar value of the sale is the price paid by the Schedule user for products and services on a Schedule task or delivery order." In the "deemed order" scheme that the Proposed Rule would establish, however, there would be no Schedule task or delivery order, and no dollar value to report, because there would be no order made under the FSS contract. The Proposed Rule would appear to require the contractor to derive the dollar value of the sale to report from a data file that the contractor would receive from the agency administering the retail pharmacy program. But the data file that the contractor would use to determine the amount of reportable sales would not be a list of orders from the FSS contracts by ordering agencies. Instead, the files would consist of agency beneficiary utilization data for each of the FSS contractor's covered drugs. We are not aware of any statutory report allowing such beneficiary utilization data (that is, a beneficiary's prescription order filled at a commercial retail pharmacy) to trigger an FSS contractor's obligation to make an IFF payment under the FSS contract. We recommend that GSA delete subsection (i) of the clause.

IV. CONCLUSION

Based on the foregoing, the Section believes that GSA lacks authority to proceed with the Proposed Rule. In particular, the Section respectfully disagrees with the GSA's conclusion that either FPASA and the VHCA, or both, authorize a federal agency to collect refunds on non-procurement transactions such as those contemplated by the Proposed Rule. For this reason, the Section recommends that GSA not proceed with the Proposed Rule.

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The Section appreciates the opportunity to comment on the Proposed Rule and is available to provide any additional information or assistance as you may require.

Sincerely,

Patricia H. Wittie

Patricia H. Wittie
Chair, Section of Public Contract Law

Enclosure

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January 28, 2004

Via UPS Overnight and Facsimile

William Winkenwerder, Jr., MD
Assistant Secretary of Defense for Health Affairs
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Washington, DC 20301-1200

Re: Procurement Of Covered Drugs Under The TRICARE Retail Pharmacy Benefit Program

Dear Dr. Winkenwerder:

On behalf of the Section of Public Contract Law of the American Bar Association (the "Section"), including its Health Care Contracting Committee, I am submitting comments on the above-referenced matter. The Section consists of attorneys and associated professionals in private practice, industry and Government service. The Section's governing Council and substantive committees contain members representing these three segments, to ensure that all points of view are considered. In this manner, the Section seeks to improve the process of public contracting for needed supplies, services and public works.

The views expressed herein have not been approved by the House of Delegates or the Board of Governors of the American Bar Association and, therefore, should not be construed as representing the policy of the American Bar Association.

I. Summary

The Section's comments address the Department of Defense's ("DOD") proposed TRICARE Retail Pharmacy Benefit Program ("TPBP"), as detailed in an

August 6, 2003 letter (enclosed) from you to a trade association (the "DOD Letter"). Among other things, the DOD letter outlines the legal basis for requiring pharmaceutical manufacturers ("manufacturers") to pay rebates to the DOD for purchases of covered drugs by DOD beneficiaries from retail pharmacies. The Section understands that DOD and Department of Veteran's Affairs ("VA") personnel have been discussing this topic in various forums, including a VA presentation made last fall at a seminar on the Veterans Health Care Act sponsored by the Section's Health Care Contracting Committee. Although the DOD Letter was not addressed to the Section, the letter articulates the agency's position in detail and therefore serves as a useful vehicle for the Section to express its views on certain procurement issues.

The DOD Letter included a diagram of the proposed structure of the TPBP, which is also enclosed. Although the proposed structure of the TPBP may raise other legal issues, the Section's comments respond only to DOD's position that the purchase of the covered drugs by DOD beneficiaries from a retail pharmacy constitutes the acquisition of supplies from the manufacturers under federal procurement laws and regulations. For the reasons explained herein, the Section respectfully disagrees.

The Veterans Health Care Act of 1992 ('VHCA") requires the "acquisition" or "procurement" of covered drugs in order for DOD or another authorized federal agency to gain the benefit of the statutory discount available under the VHCA. An acquisition or procurement of covered drugs by a federal agency requires a contract under which title to the supplies passes to a federal agency. No such contract exists between DOD and a manufacturer. In addition, according to the diagram attached to the DOD Letter, no privity of contract exists between the manufacturer and DOD in connection with sales of covered drugs through retail pharmacies. Moreover, neither the Federal Supply Schedule ("FSS") contracts nor the Master Agreement between the VA and each manufacturer includes provisions addressing sales of covered drugs through retail pharmacies as contemplated under the TPBP. We also understand that not all payments to the retail pharmacies involve appropriated funds as required under a federal procurement contract. In sum, the Section does not believe the VHCA changed the legal requirements and fundamental norms characterizing a federal procurement. The Section encourages DOD to reconsider its position that the sale of covered drugs through retail pharmacies constitutes a procurement of supplies by a federal agency under applicable procurement laws and regulations, including the VHCA and to investigate alternate means to achieve its ends.

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II. Background

The VHCA authorizes certain agencies, including the DOD and the VA, to receive certain statutory discounts when procuring covered drugs. Under the VHCA, manufacturers enter into a "Master Agreement" with the VA under which a manufacturer agrees to make available its covered drugs at the discounted price (called the Federal Ceiling Price or "FCP") for procurement under a FSS contract or that are "purchased under depot contracting systems . . .." 38 U.S.C. § 8126(a)(2). The VHCA defines the term "depot" as follows:

> The term "depot" means a centralized commodity management system through which covered drugs procured by an agency of the Federal Government are—
>
> (A) received, stored, and delivered through—
>
> (i) a federally owned and operated warehouse system, or
> (ii) a commercial entity operating under contract with such agency; or
>
> (B) delivered directly from the commercial source to the entity using such covered drugs.

38 U.S.C. § 8126(h)(3). We understand that DOD relies on the alternative definition of depot in part (B) of this definition to support its position that DOD is procuring covered drugs when such drugs are purchased by DOD beneficiaries directly from retail pharmacies.

According to the DOD Letter, the TPBP will be implemented "through a centralized commodity management system (PBO) through which covered drugs will be procured by DOD using appropriated funds for use of its beneficiaries and delivered directly from the commercial source." The term "PBO" refers to DOD's Pharmacy Benefits Office that will be established to manage the TPBP with the assistance of a contracted commercial Pharmacy Benefits Manager ("PBM"). The PBM will provide its network of contracted retail pharmacies to dispense drugs to the TRICARE beneficiaries as shown in the attachment to the DOD Letter.

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According to the diagram attached to the DOD Letter, retail pharmacies acquire covered drugs through the normal commercial sales channel. The manufacturer sells its covered drugs to a wholesaler, which in turn sells the covered drugs to one of the retail pharmacies participating in the PBM's network of contracted pharmacies. Beneficiaries under DOD's TRICARE program will purchase covered drugs directly from these retail pharmacies. The retail pharmacy will transmit pharmacy claims data to the PBM, which in turn pays the claim and transmits consolidated claims data to the PBO. The consolidated claims data will, generally speaking, indicate the volume of covered drugs purchased by DOD beneficiaries. The PBO will use this utilization data to request a rebate from the manufacturer that reflects DOD's alleged entitlement to the lower of the FCP or the FSS price for such utilization.

III. The Proposed Depot Contracting System Does Not Result In A Procurement Of Covered Drugs By A Federal Agency

The DOD Letter characterizes the TPBP mechanism described above as a procurement by DOD so as to trigger the VHCA. Specifically, DOD maintains that covered drugs will be "procured" through a "centralized commodity management system" using "appropriated funds for use of its beneficiaries and delivered directly from the commercial source." DOD Letter at 3.

There appears to be no dispute that a procurement of covered drugs must occur for DOD to be entitled to the statutory discounts under the VHCA. The VHCA expressly refers to the procurement of covered drugs when discussing the two delivery mechanisms, specifically the FSS contracts and a depot contracting system. The VHCA provides that "the manufacturer of covered drugs shall make available for *procurement* on the Federal Supply Schedule of the General Services Administration each covered drug of the manufacturer." 38 U.S.C. § 8126(a)(1) (emphasis added). Similarly, the VHCA definition of a "depot" includes a requirement that "covered drugs [be] *procured* by an agency of the Federal Government . . .." 38 U.S.C. § 8126(h)(3) (emphasis added).

The DOD Letter acknowledges that the "laws and regulations relating to the acquisition authority of DOD generally refer to procurement or acquisition as the acquiring of supplies or services by contract with appropriated funds by and for the use of the Federal Government." DOD Letter at 3. For the reasons below, however, the purchase of covered drugs by a beneficiary from a retail pharmacy

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does not meet the definition of a procurement or acquisition under these laws and regulations.

A. No Contract Exists Between The Manufacturer And DOD For Sales Of Covered Drugs Through Retail Pharmacies

First, a procurement or acquisition requires a contract between the federal agency and the seller, which in this case is the manufacturer. The Office of Federal Procurement Policy Act defines the term "procurement" as including "all stages of the process of acquiring property or services, beginning with the process for determining a need for property or services and ending with *contract* completion and closeout." 41 U.S.C. § 403(2) (emphasis added). Likewise, the Federal Acquisition Regulation ("FAR") defines the term "acquisition" as meaning "the acquiring *by contract* . . . of supplies or services . . .." FAR 2.101(2)(emphasis added). A fundamental norm underlying contract law is that a buyer and seller of goods share privity of contract.[1] As the diagram attached to the DOD Letter shows, there is no privity of contract between DOD and the manufacturer as the seller of the covered drugs. At least five separate transactions of money and product occurs under DOD's proposed scheme. None of these transactions involves a contractual agreement between the manufacturer and DOD. In the absence of the requisite privity of contract between DOD (or its authorized agent) and the manufacturer (or its authorized agent), there is no procurement from the manufacturer to which the provisions of the VHCA can attach.[2]

The proposed arrangement stands in contrast to the commercial practice with managed care companies that DOD apparently desires to replicate. In those

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[1] See, e.g., Etchey v. United States, 15 Cl. Ct. 152, 154 (1988) (defining privity of contract as "that connection or relationship which exists between two or more contracting parties").

[2] See United States v. Johnson Controls, Inc., 713 F.2d 1541, 1550 (Fed. Cir. 1983). An exception to the general subcontractor privity rule exists if the prime contractor is acting as merely a government agent, thereby establishing a relationship between a subcontractor and the government. Id. The exception does not apply in this case. To establish an agency relationship one needs to prove that the prime contractor: (1) is acting as a purchasing agent for the government; (2) the agency relationship between the government and prime contractor was established by clear and contractual consent; (3) the contract stated that the government would be directly liable to vendors for the purchase price. Id. at 1551. Under the current structure of the TPBP, the manufacturer did not consent to providing FCP/FSS prices for the TRICARE beneficiaries. Also, the PBM will make payments on DOD's behalf, but the Government will not be directly liable to pay a purchase price to the pharmacy's supplier.

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situations, the manufacturers often pay chargebacks and rebates for drugs indirectly purchased by a managed care company or PBM through a wholesaler. In those cases, however, a contractual agreement exists between the manufacturers and a managed care company or PBM that establishes the terms and conditions associated with those forms of discounting practices. Likewise, a contractual agreement exists between the manufacturer and the wholesaler for the latter to submit a chargeback to the manufacturer if the wholesaler sold the drug to a managed care company or PBM at a lower price than the wholesaler paid to the manufacturer. In contrast, the two contracts implementing the VHCA – the Master Agreement and FSS contracts – do not contain any term or condition authorizing indirect sales through retail pharmacies or the payment of rebates. DOD appears to authorize such indirect sales and payments and does not cite any existing provision in either of these agreements to support its position.

B. Title To The Covered Drugs Sold Through Retail Pharmacies Does Not Pass To The Government

Second, another fundamental procurement norm is that title to the supplies must pass from the seller to the buyer when supplies are being purchased (as opposed to being leased, for example). Under the Uniform Commercial Code ("U.C.C."), a "sale" is defined as "passing of title from the seller to the buyer for a price . . .." U.C.C. § 2-106(1). Similarly, the FAR contains a requirement to pass title to the government. For commercial items such as the covered drugs, the requirement for title to pass is reflected in FAR 52.212-4, which provides that "[u]nless specified elsewhere in this contract, title to items furnished under this contract shall pass to the Government upon acceptance, regardless of when or where the Government takes physical possession." Under the proposed structure of the TPBP, DOD neither accepts nor takes physical possession of the covered drugs at any time.[3] Stated otherwise, DOD's position violates the long-established

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[3] The U.C.C. also requires that "[t]itle to goods cannot pass under a contract for sale prior to their identification to the contract (Section 2-501)." U.C.C. § 2-401(1). Under the proposed TPBP, the covered drugs are never identified to any contract between the Government and the manufacturer. If a "contract is for the sale of future goods," identification under the U.C.C. "occurs when the goods are shipped, marked or otherwise designated by the seller as goods to which the contract refers." U.C.C. § 2-501(1)(b). Under the proposed TPBP, the manufacturer never designates the covered drugs to be sold to DOD or any DOD beneficiary. Although the U.C.C. does not directly apply to federal procurements, its provisions regarding the sale of goods is instructive regarding when title passes to goods under FAR 52.212-5 for commercial items.

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procurement norm that when purchasing supplies, the government must obtain title at some point in the transaction.

C. DOD Uses Non-Appropriated Funds

Third, procurements must involve the payment of appropriated funds. FAR 2.101(b)(2) ("[a]cquisition means the acquiring by contract *with appropriated funds* . . .") (emphasis added). We understand that non-appropriated funds in the Medicare Retiree Health Care Fund will be used to pay some of the claims submitted by TRICARE Retail Pharmacies.[4]

In addition, member and other third party payment will be involved in most if not all of these transactions due to coverage limitations, co-pays, coordination of benefits, etc. Therefore, appropriated funds will not be used to purchase the drugs. Instead, appropriated funds will only be used to reimburse a portion of the cost of the drugs based on the benefit structure provided under the health coverage and other third parties' liability related to the beneficiary's individual facts and circumstances (e.g., coordination of benefits). Finally, it is our understanding that if the guaranteed discount level is not achieved by the PBM, the excess price above the guaranteed discount will be deducted from the PBM's administrative fee up to the full value of the PBM contract price. As a result, a portion of the price of the drug under the current structure could be paid by the PBM.

D. The Terms And Conditions Of The FSS Contract Do Not Correspond To The Manner Of Sale Under The TPBP

Fourth, assuming *arguendo* that retail sales of covered drugs occur under a FSS contract,[5] the proposed TPBP does not involve reimbursement to retail pharmacies for items that are listed on the FSS contract. The FSS contract establishes prices for certain contracted line items known as stock keeping units ("SKUs"). Each SKU has a unique eleven-digit National Drug Code ("NDC") number. There may be multiple SKUs for the same product to reflect market demand for various package sizes. FCPs are calculated only for the same 11-digit

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[4] See Budget Justification, available at www.dod.mil/comptroller/defbudget/fy2003/ budget justification.

[5] We understand that DOD maintains that the covered drugs to be procured under the depot contracting system will be sold under FSS contracts. On that note, we further understand that the VA intends to collect an industrial funding fee on each covered drug sold through a retail pharmacy.

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NDC contract line items. The entities that purchase from the wholesaler, *e.g.*, retail pharmacies, break the SKUs down into dispensing units for resale or for their own use. At the same time, retail pharmacies establish what price to charge for dispensed prescriptions based on numerous factors, including negotiated arrangements with health plans and dispensing fees. The units dispensed by retail pharmacies are not traceable to a particular SKU or NDC on the FSS contract and in many cases are not traceable to a particular wholesaler or commercial distribution channel. In fact, dispensed units could have been obtained through a number of sources, including unauthorized secondary markets, and at unknown prices. For these reasons, it would not be possible to determine a rebate amount for a dispensed unit of drug by reference to the FSS price for a contracted SKU.

Moreover, FSS contracts are indefinite quantity, indefinite-delivery contracts that require the issuance and acceptance of purchase or delivery orders to effectuate a transaction. No such orders occur under the proposed TPBP mechanism. In addition, we understand that the contracted retail pharmacies will not act as agents of DOD and do not have authority to purchase under the FSS contract. Likewise, neither the wholesaler or retail pharmacy are agents of the manufacturer selling FSS contracted products to authorized DOD users. There is no transaction contemplated in the proposed arrangement that would qualify as an order under an FSS contract. This is an essential requirement for an authorized user to obtain supplies under FSS contracts.

Based on the preceding discussion, DOD's proposed retail pharmacy program is not a procurement or acquisition of covered drugs by a federal agency, and DOD has no authority to seek rebates from pharmaceutical manufacturers in connection with purchases of covered drugs by DOD beneficiaries under this program.

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IV. Conclusion

Notwithstanding the foregoing, there may be alternative ways to structure the TPBP so that the program falls within statutory requirements. To that end, as a Section comprised of procurement professionals in private practice, industry, and government service, we encourage the relevant stakeholders to work together to find such alternatives. Please consider the Section and its Health Care Contracting Committee as a potential resource in connection with such an effort. The Section's main concern is the potential unauthorized expansion of legally prescribed definitions of "procurement" and "acquisition." Acquisition of supplies and services by a third party not acting as an agent of the federal government is not a procurement as that term currently is defined under the law. The VHCA does not change this definition.

Sincerely,

H. J. Bell, Jr.

Hubert J. Bell, Jr.
Chair, Section of Public Contract Law

Enclosure

cc: Patricia H. Wittie
Robert L. Schaefer
Michael A. Hordell
Patricia A. Meagher
Mary Ellen Coster Williams
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Co-Chairs and Vice Chairs of
the Health Care Contracting Committee
David Kasanow

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THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

AUG - 6 2003

Mr. Richard I. Smith
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1100 Fifteenth Street, NW
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Dear Mr. Smith:

This is in response to your recent letter on behalf of members of the Pharmaceutical Research and Manufacturers of America (PhRMA) regarding the new TRICARE Retail Pharmacy Program and the current Department of Defense (DoD) solicitation for a TRICARE Retail Pharmacy contract. I understand that identical letters were also sent to Dr. Robert H. Roswell, Under Secretary for Health, Department of Veterans Affairs (VA), Ms. Phillipa L. Anderson, Assistant General Counsel, VA, and Mr. Robert Seaman, General Counsel, TRICARE Management Activity (TMA).

Your letters assert that the TRICARE Retail Pharmacy Program involves a commercial reimbursement arrangement, and not a procurement by DoD, and as such is unlawful under current statutes. It appears that your concerns are based on a misunderstanding of the Department's new TRICARE Pharmacy Benefits Program and DoD's acquisition of drugs under the retail portion of that Program.

As noted in your letter, manufacturers are statutorily required under the Veterans Health Care Act of 1992 (VHCA) to make their covered drugs available at or below federal ceiling prices (FCPs) for procurement by the VA, DoD, the Public Health Service and the U.S. Coast Guard. Such procurements may be under Federal Supply Schedule (FSS) contracts or depot contracting systems administered by Federal agencies.

TRICARE Pharmacy Benefits Program (TPBP)

A new TPBP has been developed and will be implemented in lieu of the current retail pharmacy program operating under the current generation of TRICARE Managed Care Support Contracts. Section 703 of the Strom Thurmond National Defense Authorization Act for Fiscal Year 1999, Public Law 105-261, required the Secretary of Defense to plan a "system-wide redesign of the military and contractor retail and mail-order pharmacy system of the Department of Defense by incorporating 'best business practices' of the private sector." Subsequently, section 701 of The National Defense Authorization Act for Fiscal Year 2000, Public Law 106-65, directed the Secretary of Defense to "establish an effective, efficient, integrated pharmacy benefits program ...." The re-engineered TPBP was developed consistent with these mandates and will include, among others, a uniform formulary, implementation of the Pharmacy

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Data Transaction Service (PDTS), and a pharmaceutical and therapeutics committee. A final regulation implementing the TPBP will be published in the near future as title 32, Code of Federal Regulations, Section 199.21.

The new TPBP will be administered through a government office, preliminarily known as a Pharmacy Benefits Office (PBO), which will manage the TRICARE pharmacy benefit using the PDTS and a single TRICARE Retail Pharmacy contract for a Pharmacy Benefit Manager (PBM). The PBM will be paid a negotiated administrative (transaction) fee for performance of certain services under the contract; however, the fee will not be related, directly or indirectly, to DoD's acquisition costs under federal pricing. Enclosed for your information is a diagram of the process as it will operate.

The PBM will be tasked with providing a retail pharmacy network and performing services as a fiscal intermediary by using DoD appropriated funds (either Defense Health Program funds or the accrual "Fund" established under chapter 56, title 10, United States Code) to pay for all TRICARE prescriptions once the PBO verifies the individual beneficiary's eligibility and authorizes payment. Consistent with legislative mandate, administration of the TPBP will preserve best commercial practices by allowing a retail pharmacy to obtain its supply of drugs as it normally does in the commercial world. Retail pharmacies may purchase their supplies from a wholesaler, or in certain instances, directly from the manufacturer. This avoids DoD having to create unnecessary warehousing/distribution facilities and is consistent with current government procurement and inventory practices generally known as "just-in-time delivery."

A network retail pharmacy will communicate directly with the PBM on each individual request to fill a prescription by a TRICARE beneficiary. The PBM will interface with the PBO for beneficiary eligibility, clinical adjudication, and application of TPBP rules – all in real time before the prescription is filled. The PBO will manage the TPBP through the PDTS to verify beneficiary eligibility, check for potential drug interactions, and authorize payment of each prescription. The PBM will authorize the network retail pharmacy to fill the prescription and receive appropriate co-payments from the patient. The PBM will then receive specific authorization to draw funds from an appropriate government account to issue payment to the network pharmacy based on a negotiated network rate (e.g., AWP pricing less a discount) less the patient's co-payment and plus a dispensing fee.

Unlike the current retail pharmacy program under existing TRICARE Managed Care Support Contracts, DoD will work directly with the manufacturer to receive rebates based on federal pricing. The PBO will be able to ensure that every purchase made under the TPBP was for an eligible TRICARE beneficiary for a covered benefit and will give pharmaceutical manufacturers itemized information, using the PDTS, on drugs procured under TRICARE. In turn, the appropriate manufacturers would provide rebates directly to DoD for deposit into the TRICARE appropriations with assurance that the rebates based on FCPs (or FSS, whichever is lower) only apply to prescriptions filled for eligible DoD beneficiaries.

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Department of Defense Procurement

Briefly, under the VHCA, FCPs are required by section 38 U.S.C. § 8126(a)(2) "... with respect to each covered drug of the manufacturer procured by [DoD] ... that is purchased under depot contracting systems ...." The statute, at § 8126(h)(3), defines "depot" as:

> "... a centralized commodity management system through which covered drugs procured by an agency of the Federal Government are –
>
> (A) received, stored and delivered through –
>
> (i) a federally owned and operated warehouse system, or
> (ii) a commercial entity operating under contract with such agency; or
>
> (B) delivered directly from the commercial source to the entity using such covered drugs."

It is true that the Department of Veterans Affairs (VA) previously determined that the retail pharmacy program under the current generation of TRICARE Managed Care Support Contracts is not considered a DoD procurement of drugs. However, the new TPBP has been reviewed by VA, and VA has determined that the retail portion of the new TPBP qualifies for FCPs because such purchases will be a procurement by DoD under a depot contracting system as defined in 38 U.S.C. § 8126(h)(3).

The TPBP will be implemented in a manner meeting the specific words of the VHCA; i.e., through a centralized commodity management system (PBO) through which covered drugs will be procured by DoD using appropriated funds for use of its beneficiaries and delivered directly from the commercial source. The term "procured" is not defined in 38 U.S.C. § 8126; however, laws and regulations relating to the acquisition authority of DoD generally refer to procurement or acquisition as the acquiring of supplies or services by contract with appropriated funds by and for the use of the Federal Government.

In compliance with the above applicable definition and 38 U.S.C. § 2816, the TRICARE Pharmacy Benefits Program (TPBP) will involve DoD procurement of covered drugs "purchased under depot contracting systems ...." The VA specifically agrees that the TPBP is, in reality, a system for the acquisition, delivery, and distribution of prescriptions by DoD on behalf of its beneficiaries through the use of a DoD Pharmacy Benefits Office and a contracted PBM with a retail pharmacy network. The VA agrees that the TPBP method of acquisition meets the alternative definition of "depot" under 38 U.S.C. § 8126(h)(3)(B).

The VA also supports the DoD position that FSS contract prices are applicable to retail network TRICARE prescriptions under the new TPBP (where such prices are lower than FCPs) in that the FSS drugs are being procured by the DoD PBO, part of an executive Government agency entitled to access the FSS. Because the PBO, not the contracted PBM, is procuring

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beneficiaries' drugs, there is no need for implementing procedures under FAR Part 51 to issue an authorizing letter to the PBM.

Policy Concerns

Your letter raises a concern with the complexities involved in implementing a "rebate" process under the TPBP. We recognize the concern and are willing to work with the manufacturers to address the complexities. If helpful, TMA is willing to provide current utilization data to assist your members and other pharmaceutical manufacturers in addressing their operational needs to ensure success of the program. I understand that representatives of TMA and VA intend to meet with representatives of manufacturers in the near future on this issue.

Your letter also expresses an opinion that this new TPBP represents an expansion of federal pricing beyond authorized users. It is DoD's position that this new TPBP does not represent an expansion of statutory authority, merely the expanded use by DoD of authority already given to DoD by statute. Maintaining the status quo whereby manufacturers have been the beneficiary of windfalls because DoD has not fully exercised its statutory entitlement to federal pricing is no barrier to DoD's expanded use of its existing authority.

Your letter also notes your concerns regarding implementation of the DoD Uniform Formulary and advises that the concerns were raised in comments in response to public rule making procedures. Those concerns will be appropriately addressed as part of publication of the final rule.

In summary, it is the opinion of DoD and VA that the TPBP is, in reality, a system for the acquisition, delivery, and distribution of prescriptions by DoD on behalf of its beneficiaries through the use of a DoD Pharmacy Benefits Office and a contracted PBM with a retail pharmacy network, and that the TPBP method of acquisition meets the alternative definition of "depot" under 38 U.S.C. § 8126(h)(3)(B). Further, FSS contract prices are applicable to retail network TRICARE prescriptions under the new TPBP (where such prices are lower than FCPs) in that the FSS drugs are being procured by the DoD PBO, part of an executive Government agency entitled to access the FSS. This response has been shared with VA officials, including the VA Office of General Counsel, and I understand that they have no objections to the content of this letter.

Sincerely,

William Winkenwerder, Jr., MD

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Enclosure:
TRICARE Retail Pharmacy Diagram

cc: w/enclosure
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Department of Veterans Affairs

Ms. Phillipa L. Anderson
Assistant General Counsel
Department of Veterans Affairs

Mr. Robert D. Seaman
General Counsel
TRICARE Management Activity

TRICARE Retail Pharmacy